

EPA REGISTRATION NUMBER 91090-3

PROCESSING REQUEST

Reg # 91090-G

Decision # 503658

Description: New product registration

Electronic Label & Letter
(see PPLS)

OR

Non Electronic
Label & Letter
(Scanning required)

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 11-23-2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Rita Kumar

Division: RD

Phone: 703-308-8291

Date: 5-19-16



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

91090-3

Date of Issuance:

3/28/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 03/28/2018

Name of Pesticide Product:

Neove Spot On #001 for Dogs

Name and Address of Registrant (include ZIP Code):

Janelle Kay
Shanghai Neway Animal Health Co., Ltd.
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

3/28/16

2. This registration is time-limited and expires 03/28/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 91090-3."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/23/2015

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Enclosure

MASTER LABEL: This master label includes label text for different size packages and application rates specific to the pet's age and body weight

{Front Panel}

{Note to Reviewer: The word Dog will be at least 40-75% in height of the largest letter in the primary brand name. A large clear picture of a dog in the respective weight range will be on the front panel of the label.}

Neove Spot On #001 for Dogs

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

Alternate Brand Names

ImidaCare for Dogs [& Puppies]

ImidaStar for Dogs [& Puppies]

PetImida for Dogs [& Puppies]

ACCEPTED

Mar 28, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 91090-3

Once a Month Topical Flea and Lice Treatment

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)

OR

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)

{Picture of a dog in the weight range for the product as packaged will be included in the final labeling}

READ THE ENTIRE LABEL BEFORE EACH USE

{Optional marketing claims follow:}

- [One treatment prevents further flea infestation for at least four weeks]
- [Kills fleas on dogs within 12 hours]
- [Kills fleas before they lay eggs]
- [Convenient, easy to apply]
- [Kills [biting, chewing] lice]
- [For treatment and prevention of [biting, chewing] lice [infestations]]
- [Controls existing [biting, chewing] lice infestations]
- [Dual protection (against fleas and lice)]
- [Treats, prevents and controls [biting, chewing] lice [infestations]]
- [Provides effective control of [biting, chewing] lice [infestations]]
- [Kills [biting, chewing] lice and prevents further infestations]
- [For treatment and prevention of infestations with [biting, chewing] lice]
- [Waterproof]
- [Fragrance free]

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0

{Front Panel, cont.}

EPA Est. No. 091090-XXX-X

EPA Reg. No. 091090 -XXX

NET CONTENTS: [3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.034 fl. oz. (1.0 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.084 fl. oz. (2.5 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)

KEEP OUT OF REACH OF CHILDREN
WARNING

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.

{Note to reviewer: cat icon will be 1.5 cm x 1.5 cm and will appear on the lower right hand corner of the front panel}



{Back Panel}

Once a Month Topical Flea and Lice Treatment	
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)	
OR	
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)	
OR	
For Use only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)	
OR	
For Use only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)	

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency medical treatment information, call 1-800-222-1222. To Physician: Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS**

WARNING Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

{Back Panel}

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing 4 – 10 lbs (0.4 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 11 – 20 lbs (1.0 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 21 – 55 lbs (2.5 ml tube)
OR
Use only on dogs 7 weeks and older and weighing Over 55 lbs (4.0 ml tube)
- Do not use on animals other than dogs.
- Do not apply to puppies or dogs under 7 weeks of age and weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do allow the product in the dog's eyes.
- Do not allow children to apply this product.
- Do not allow your dog to ingest this product.
- Do not reapply for 4 weeks.
- Use entire contents of tube on each dog. Do not split one tube between two dogs.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after product has been applied.

[Back Panel]

{Note to reviewer: this box will be located on the lower right hand corner of the back panel}

Side Effects Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

{Note to reviewer: this box will be located on the lower right hand corner of the back panel, below the Side Effects box} DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



Icon size 1.5cm x 1.5cm

Manufactured For
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

[Made in China]

Lot No.:

{Insert}

Once a Month Topical Flea and Lice Treatment**For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)****DIRECTIONS FOR USE****READ THE ENTIRE LABEL BEFORE EACH USE**

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as show. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.

Visuals depicting how to open blister pack

3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN BLISTER PACK"
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the contents directly on the skin. Apply the entire contents of the tube between the shoulder blades of the dog. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.

Visuals depicting Application to Animal

4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation,

retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for effective control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

{Label on Individual Tube}

Neove Spot On #001 for Dogs

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

Lot No. 0000000

{Label on Blister Pack}

Neove Spot On #001 for Dogs

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

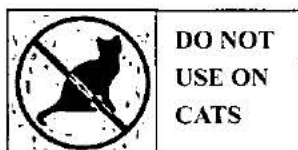
Lot No. 0000000

[3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR

[3][4][6][8] Tubes each 0.034 fl. oz. (1.0 ml) OR

[3][4][6][8] Tubes each 0.084 fl. oz. (2.5 ml) OR

[3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)



Kumar, Rita

From: Kumar, Rita
Sent: Monday, March 28, 2016 2:46 PM
To: Eagle, Venus
Subject: FW: PM review requested 091090-00003 D503658 new dog spot-on registration
Attachments: 091090-00003 D503658 letter.docx; 091090-00003 D503658 label v2.pdf

Importance: High

Venus: here is a resend of this registration, with revised label. Hope this will be okay.
Rita

From: Kumar, Rita
Sent: Monday, March 28, 2016 9:41 AM
To: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: PM review requested 091090-00003 D503658 new dog spot-on registration

Please see attached. PRIA date is tomorrow.
Thanks,
Rita

Kumar, Rita

Resubmission:

S

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Sunday, March 27, 2016 11:25 PM
To: Kumar, Rita
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application
Attachments: 91090-G.20160326.Shanghai Neove Spot on label_revised (tracked).pdf; 91090-G.20160326.Shanghai Neove Spot on label_revised (clean).pdf

Rita,

Attached is the tracked and clean versions of the label are attached. Let me know if you have any further questions or changes.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 253-853-7369
(F): 253-853-5516
(E): Janelle@PyxisRC.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Friday, March 25, 2016 8:44 AM
To: Janelle Kay <Janelle@PyxisRC.com>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application
Importance: High

Dear Janelle: Please see minor label comments below, refer to highlighted label for page numbers:

1. Front Panel: Add a Master Label statement in a box on the front panel that reads something like this: "This master label includes label text for different size packages and application rates specific to the pet's age and body weight."
2. Front Panel: Add a note to reviewer below product name, stating:
 - The word Dog will be at least 40-75% in height of the largest letter in the primary brand name.
 - A large clear picture of a dog in the respective weight range will be on the front panel of the label.
3. On page 3, the First Aid box should be placed above Precautionary Statements. Also, under Notes in the First aid box, provide a phone number as contact for emergency medical treatment information. This may be the company's number or NPIC contact information.
4. On page 4, under Hazards to Domestic Animals, delete "while rare" from the second sentence. Also indicate a panel (Back Panel?) on top of pages 4 and 5.
5. On page 4, under Restrictions, the last bullet must indicate correct spelling for the word "cats".

6. A batch code must appear on either the front panel or back panel. On page 6, How to Apply, we would like to see the visual depicting application to animal. Otherwise, clearly state in #3 that entire contents of the tube must be applied as spot between the shoulder blades.

Submit revised labeling to me ASAP, preferably today, so that we can wrap up this registration on Monday.

Regards,
Rita

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Thursday, March 24, 2016 12:00 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Dear Rita,

Please see attached. Fair disclosure: we inherited the application for registration from another consultant so the formatting was difficult to work with (as was tracking changes), but hopefully this will do the trick for you.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Thursday, March 24, 2016 6:07 AM
To: Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Hi Janelle; can you please send me a highlighted copy of this revised label? Thanks,
Rita

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Wednesday, March 23, 2016 8:07 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Subject: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Rita,

Attached please find Shanghai Neway's response to the Agency's pre-decisional letter dated March 15, 2016 related to Neove Spot On #001 for Dogs (EPA File Symbol 91090-G). In sum, Shanghai Neway is accepting all of EPA's requested changes and believes it has complied in full with EPA's requested changes. However, if we have overlooked or misunderstood a request, please don't hesitate to contact me. ***Please let me know if this email submission is sufficient or if you would prefer we also submit a hard copy and/or through CDX.***

While Shanghai Neway has accepted the weight range change from 3.5 to 4 lb, we would like a copy of the safety review as we noticed that Bayer has 3.5 lb on its label. This could simply be a matter of data cited, but we would like the information to consider in case Shanghai Neway decided to submit an amendment to revise it to 3.5 lb at a later date. If you could send that at your convenience, that would be great.

Let me know if you have any questions or additional changes on the pending application.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

Kumar, Rita

From: Kumar, Rita
Sent: Friday, March 25, 2016 11:44 AM
To: 'Janelle Kay'
Cc: Eagle, Venus
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Importance: High

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Regards,
Rita

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Sent: Thursday, March 24, 2016 12:00 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

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Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW

Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Thursday, March 24, 2016 6:07 AM
To: Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Hi Janelle; can you please send me a highlighted copy of this revised label? Thanks,
Rita

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Wednesday, March 23, 2016 8:07 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Subject: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application

Rita,

Attached please find Shanghai Neway's response to the Agency's pre-decisional letter dated March 15, 2016 related to Neove Spot On #001 for Dogs (EPA File Symbol 91090-G). In sum, Shanghai Neway is accepting all of EPA's requested changes and believes it has complied in full with EPA's requested changes. However, if we have overlooked or misunderstood a request, please don't hesitate to contact me. ***Please let me know if this email submission is sufficient or if you would prefer we also submit a hard copy and/or through CDX.***

While Shanghai Neway has accepted the weight range change from 3.5 to 4 lb, we would like a copy of the safety review as we noticed that Bayer has 3.5 lb on its label. This could simply be a matter of data cited, but we would like the information to consider in case Shanghai Neway decided to submit an amendment to revise it to 3.5 lb at a later date. If you could send that at your convenience, that would be great.

Let me know if you have any questions or additional changes on the pending application.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

NEWAY

March 15, 2016

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc., and its employees listed below:

Janelle Kay	Ann Tillman
Michael Kellogg	Leanne Pruett
Jennifer Yentel	Nicole O'Loughlin

is authorized to act as agent for Shanghai Neway Animal Health Co., Ltd. (EPA Company Number 91090), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registration, Neove Spot On #001 (EPA File Symbol 91090-G), pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Zane Liu
President

cc: Pyxis Regulatory Consulting, Inc.

Shanghai Neway Animal Health Co., Ltd.

Rm 509, 1438 Shan Xi Bei Rd, Shanghai, China, 200060

Tel: 86 21 5187 7909 Fax: 86 21 6148 4508

Website: www.newaypharm.com.cn

Kumar, Rita

Resubmission:
S 983551

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Wednesday, March 23, 2016 8:07 PM
To: Kumar, Rita
Subject: Shanghai Neway (91090-G) Response to pre-decisional letter for pending application
Attachments: 20160315 Revised LOA (Neway).jpg; 20160318 Agency matrix.pdf; 20160318 Neove Spot On #001 (91090-G) 8570-1_signed.pdf; 20160318 Public matrix.pdf; 20160323 Cover letter_signed.pdf; 20160323 label certification.pdf; 91090-G.20160318.Shanghai Neove Spot on label_revised (clean).pdf

Rita,

Attached please find Shanghai Neway's response to the Agency's pre-decisional letter dated March 15, 2016 related to Neove Spot On #001 for Dogs (EPA File Symbol 91090-G). In sum, Shanghai Neway is accepting all of EPA's requested changes and believes it has complied in full with EPA's requested changes. However, if we have overlooked or misunderstood a request, please don't hesitate to contact me. ***Please let me know if this email submission is sufficient or if you would prefer we also submit a hard copy and/or through CDX.***

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Let me know if you have any questions or additional changes on the pending application.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. Ct. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

March 23, 2016

ELECTRONIC DELIVERY

Venus Eagle/Rita Kumar (PM 1)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: Shanghai Newway Animal Health Co., Ltd.
Neove Spot On #001 for Dogs (EPA File Symbol 91090-G)
Response to EPA's Letter Dated March 15, 2016

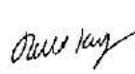
Dear Ms. Eagle/Ms. Kumar,

On behalf of Shangai Newway Animal Health Co., Ltd. (SNAH), we are submitting the following revised documents in response to EPA's letter dated March 15, 2016:

1. Revised Application for Pesticide Registration (EPA Form 8570-1), Confidential Statement of Formula (CSF), and Data Matrix (Public and Agency Internal copies) listing the address of the U.S. agent for SNAH and the revised product name
2. Revised label incorporating the label comments listed by EPA in the March 15, 2016 Predecisional letter (clean version in PDF format)
3. Certification with Respect to Label Integrity
4. Letter of Authorization from SNAH

Please feel free to contact me by email at janelle@pyxisrc.com or by phone at (253)853-7369 if you have any questions concerning this submission or need any additional information.

Sincerely,


Digitally signed by Janelle Kay
DN: cn=Janelle Kay, o=Pyxis, ou,
email=janelle@pyxisrc.com,
c=US
Date: 2016.03.23 16:47:25 -0700

Janelle Kay

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Shanghai Neway Animal Health Co., Ltd./91090-G	2. EPA Product Manager V. Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Neove Spot On #001 for Dogs	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 11556-117 (-119, -120, -122) Product Name Advantage 10 (20,55,100) Topical Sol	

Section - II


<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.4 mL - 4.0 mL	No. per container 3, 4, 6, or 8	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.2 ml to 32.0 ml		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

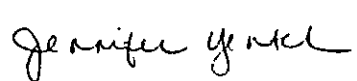
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jennifer Yentel	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature  Digitally signed by Janelle Kay DN: cn=Janelle Kay, o=Pyxis, ou, email=Janelle@PyxisRC.com, c=US Date: 2016.03.23 15:56:54 -07'00'	3. Title Agent	
4. Typed Name Janelle Kay	5. Date March 18, 2016	

25

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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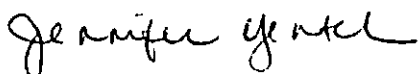
DATA MATRIX

Date March 18, 2016			EPA Reg. No./File Symbol 91090-G		Page 1 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332			Product Neove Spot On #001 for Dogs		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1600	Description of Materials Used to Produce the Product	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1670	Discussion of Formation of Impurities	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1800	Enforcement Analytical Method	49621401	Shanghai Neway Animal Health Co.	OWN	
830.6302	Color	49621402	Shanghai Neway Animal Health Co.	OWN	
830.6303	Physical State	49621402	Shanghai Neway Animal Health Co.	OWN	
Signature 			Name and Title Jennifer Yentel, Agent		Date Mar. 18, 2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

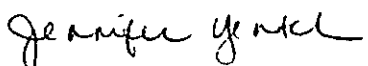
Date March 18, 2016			EPA Reg. No./File Symbol 91090-G		Page 2 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332			Product Neove Spot On #001 for Dogs		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	49621402	Shanghai Neway Animal Health Co.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility				Waiver
830.6315	Flammability				Waiver
830.6316	Explodability				Waiver
830.6317	Storage Stability	49621403	Shanghai Neway Animal Health Co.	OWN	
830.6319	Miscibility				Not required ⁴
830.6320	Corrosion Characteristics	49621403	Shanghai Neway Animal Health Co.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7050	UV/Visible Absorption				Not required ⁶
830.7100	Viscosity	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7200	Melting Point/Melting Range				Not required ⁶
Signature 			Name and Title Jennifer Yentel, Agent		Date Mar. 18, 2016

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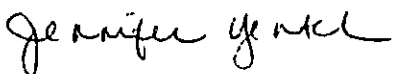
DATA MATRIX

Date March 18, 2016		EPA Reg. No./File Symbol 91090-G		Page 3 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332		Product Neove Spot On #001 for Dogs			
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Point/Boiling Range				Not required ⁶
830.7300	Density/Relative Density/Bulk Density	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7370	Dissociation Constants in Water				Not required ⁶
830.7520	Particle size, fiber length, diameter distribution				Not required
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁶
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁶
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁶
870.1100	Acute Oral Toxicity: Rat	43679601		OLD	
870.1200	Acute Dermal Toxicity: Rat	43679602		OLD	
870.1300	Acute Inhalation Toxicity: Rat	43679603		OLD	Waiver
Signature 			Name and Title Jennifer Yentel, Agent		Date Mar. 18, 2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 18, 2016			EPA Reg. No./File Symbol 91090-G		Page 4 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. Ct. NW Gig Harbor, WA 98332			Product Neove Spot On #001 for Dogs		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation: Rabbit	43679604		OLD	
870.2500	Primary Dermal Irritation	43679605		OLD	
870.2600	Dermal Sensitization	43679606		OLD	
870.7200	Companion Animal Safety	43679607 43679608 44099801 44179801		OLD OLD OLD OLD	
810.3300	Product Performance	43679609 43679610 44256901 44256902 44256903		OLD OLD OLD OLD OLD	
Generic Data Requirements					
Neove Spot On #001 qualifies for the Formulator's Exemption for imidacloprid generic data requirements.					
Signature 			Name and Title Jennifer Yentel, Agent		Date Mar. 18, 2016

Endnotes for Neove Spot On #001

¹ **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.

² **830.1700** – This product does not consist solely of the technical grade active ingredient (TGAi) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.

³ **830.6313** – These data are not required for registration of an end-use product.

⁴ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Neove Spot On #001 is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.

⁵ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.

⁶ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.

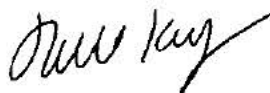
Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
91090-G	March 23, 2016	91090-G.20160318.Shanghai Neove Spot on label_revised (clean)

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature

March 23, 2016

Date

Janelle Kay
Name (typed)

Agent
Title

MASTER LABEL

[Front Panel]

Neove Spot On #001 for Dogs**For the Prevention and Treatment of Flea and Lice Infestations on Dogs****Alternate Brand Names**

ImidaCare for Dogs [& or Puppies]

ImidaStar for Dogs [& or Puppies]

PetImida for Dogs [& or Puppies]

Once a Month Topical Flea and Lice Treatment

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)**OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)****[Picture of a dog in the weight range for the product as packaged]****READ THE ENTIRE LABEL BEFORE EACH USE**

- [One treatment prevents further flea infestation for at least four weeks]
- [Kills fleas on dogs within 12 hours]
- [Kills fleas before they lay eggs]
- [Convenient, easy to apply]
- [Kills [biting, chewing] lice]
- [For treatment and prevention of [biting, chewing] lice [infestations]]
- [Controls existing [biting, chewing] lice infestations]
- [Dual protection (against fleas and lice)]
- [Treats, prevents and controls [biting, chewing] lice [infestations]]
- [Provides effective control of [biting, chewing] lice [infestations]]
- [Kills [biting, chewing] lice and prevents further infestations]
- [For treatment and prevention of infestations with [biting, chewing] lice]
- [Waterproof]
- [Fragrance free]

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0

[Front Panel, cont.]

EPA Est. No. 091090-XXX-X

EPA Reg. No. 091090 -XXX

NET CONTENTS: [3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.034 fl. oz. (1.0 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.084 fl. oz. (2.5 ml) OR

NET CONTENTS: [3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)

**KEEP OUT OF REACH OF CHILDREN
WARNING**

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.

[Note to reviewer: cat icon will appear on the lower right hand corner of the front panel]



Icon size 1.5cm x 1.5cm

[Back Panel]

Once a Month Topical Flea and Lice Treatment**For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)****OR****For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)****OR****For Use only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)****OR****For Use only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS**

WARNING Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

FIRST AID	
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
<p>To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p> <p>To Physician: Treat the patient symptomatically.</p>	

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the

labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing 4 - 10 lbs (0.4 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 11 - 20 lbs (1.0 ml tube)
OR
Use only on dogs 7 weeks and older and weighing 21 - 55 lbs (2.5 ml tube)
OR
Use only on dogs 7 weeks and older and weighing Over 55 lbs (4.0 ml tube)
- Do not use on animals other than dogs.
- Do not apply to puppies or dogs under 7 weeks of age and weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do allow the product in the dog's eyes.
- Do not allow children to apply this product.
- Do not allow your dog to ingest this product.
- Do not reapply for 4 weeks.
- Use entire contents of tube on each dog. Do not split one tube between two dogs.
- Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.
- Separate the treated dog from all other dogs and cats for 24 hours after product has been applied.

[Note to reviewer: this box will be located on the lower right hand corner of the back panel]

Side Effects Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

[Note to reviewer: this box will be located on the lower right hand corner of the back panel, below the Side Effects box] DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



Icon size 1.5cm x 1.5cm

NEOVE SPOT ON #001 for Dogs

Note: [Brackets indicate alternate language]

Manufactured For
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

[Made in China]

Once a Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 4 to 10 lbs (0.4 ml tube)
OR
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs (1.0 ml tube)
OR
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs (2.5 ml tube)
OR
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs (4.0 ml tube)

DIRECTIONS FOR USE

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as show. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.

Visuals depicting how to open blister pack

3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN BLISTER PACK"
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.

Visuals depicting Application to Animal

4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for effective control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

[Label on Individual Tube]

[Neove Spot On #001 for Dogs]

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

Lot No. 0000000

[Label on Blister Pack]

[Neove Spot On #001 for Dogs]

9.1% Imidacloprid

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 4 to 10 lbs (0.4 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 11- 20 lbs (1.0 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing 21 – 55 lbs (2.5 ml)

OR

For Use Only on Dogs and Puppies 7 Weeks or Older and Weighing over 55 lbs (4.0 ml)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

Lot No. 0000000

[3][4][6][8] Tubes each 0.014 fl. oz. (0.4 ml) OR

[3][4][6][8] Tubes each 0.034 fl. oz. (1.0 ml) OR

[3][4][6][8] Tubes each 0.084 fl. oz. (2.5 ml) OR

[3][4][6][8] Tubes each 0.135 fl. oz. (4.0 ml)

Kumar, Rita

From: Kumar, Rita
Sent: Tuesday, March 15, 2016 11:18 AM
To: 'Janelle Kay'
Cc: Eagle, Venus
Subject: Pre-decisional letter for pending application 91090-G
Attachments: image2016-03-15-111649.pdf

Importance: High

Dear Janelle: Please see attached pre-decisional letter for this pending application, and submit revised label, CSF, application form, and data matrix.

Let me know if you have any questions.

Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

MAR 15 2016

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Shanghai Neway Animal Health Co., Ltd
Rm 509, 1438 Shan Xi Bei Road
Shanghai, China

Authorized U. S. Agent: Janelle Kay
Pyxis regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: PRIA Predecisional letter – New product registration
Product Name: Neove Spot On #001
EPA File Symbol: 91090-G
Decision Number: 503658

Dear Ms. Kay:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the draft label dated March 2, 2015. The necessary label changes are specified on the attached document.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

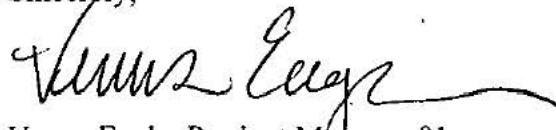
- a. You agree to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- b. You do not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- c. You withdraw the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If you inform EPA that you have concerns as described under (b) above, you will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If you agree to all of the terms of the accepted label as described in (a) above, or if you and EPA resolve any differences as described in (b), you must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to you within 2 business days following your written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Rita Kumar at kumar.rita@epa.gov or (703) 308-8291.

Sincerely,



Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs,

Attachment (1)

Attachment for Predecisional letter for 91090-G

Label Comments for 91090-G (Neove Spot-On #001)

1. Per the implementation of label changes to pet spot on products issued in 2011, the word Dog must be included as part of the product's brand name with a font size at least 75% the height of the largest letter in the primary brand name. Please change primary brand name of this product accordingly.
2. Indicate intended use(s) on the front panel, below product name.
3. Across the board, change minimum weight of dog/puppy from 3.5 lbs to 4 lbs. Cited companion animal safety studies do not support a minimum weight of 3.5 pounds.
4. All cat icons must be in yellow and black color, and appear in lower right hand corner on the front panel in compliance with 2011 pet spot on mitigation letter sent to all registrants of such products.
5. Since you have different sizes for the same product under one registration number, you must indicate tube (package) size in milliliters within () next to each body weight range, on the front panel (page 1) and elsewhere on the label.
6. On the front panel, provide Net Contents in terms of number of tubes per pack with fl.oz. (ml) for each size tube.
7. On page 6, place the Storage and Disposal statement inside a solid line box for clarity and consistency.
8. Delete the claim "Larval flea stages are killed in the dog's surroundings following contact with treated dog." Efficacy data is required to support this claim. We have also asked Bayer (registrant for the cited product) to remove this claim from similar labels, unless data is provided and found to be acceptable upon review.
9. On page 4, revise Restrictions as indicated below:
 - a. In the first bullet, revise minimum weight to 4 lbs, and correlate package (tube) size to each weight range
 - b. Revise the second bullet to read as: Do not use on animals other than dogs"
 - c. Revise the third bullet to read as: "Do not apply to puppies or dogs under 7 weeks of age and weighing less than the labeled body weight"
 - d. Add the following restrictions:
 - Do not allow children to apply this product
 - Do not allow your dog to ingest this product
 - Do not reapply for 4 weeks
 - Use entire contents of tube on each dog. Do not split one tube between two dogs.
 - Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog
 - Separate the treated dog from all other dogs and cats for 24 hours after product has been applied
10. On page 4, the Side Effects paragraph must be placed within a solid line box. Delete "although very rare" from the second sentence, this is a heightened safety claim. Side Effects box must be located on the cat prohibition icon on the lower right side of back panel.

11. On page 5, Move the title Directions for Use above "read the entire label before each use". The title Directions for Use must be in larger font and more prominent, to make it clear to user that everything that follows falls under this heading.
12. On page 6, place the Storage and Disposal statement inside a solid line box.
13. On page 6, revise the statement "Monthly treatments are required for optimal control and prevention of fleas" to read as: "Monthly treatments are required for effective control and prevention of fleas".
14. Per the implementation of label changes to pet spot on products in 2011:
 - a. The Front Panel is to have a large clear picture of a dog in the weight range for the product as packaged;
 - b. The Back Panel: Place the box labeled "Side Effects" at the lower right hand corner of the back panel.
15. On page 7, label for individual tube must indicate dog's min age and weight range in relationship to tube size.
16. Add another page indicating labeling for the Blister pack. Also indicate the number of tubes per blister pack.
17. Add U.S. address of applicant or their agent on the application form (8570-1), data matrix, and confidential statement of formula (CSF).

NEWAY

19 May 2015

Document Processing Desk (COADR)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. is authorized to represent Shanghai Neway Animal Health Co., Ltd. (EPA Company Number 91090) before the US Environmental Protection Agency in all matters regarding our Neove Spot On #001 (EPA File Symbol or Registration Number: 91090-G) producing establishment registration, registrations and applications for registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Zane Liu
President

cc: Janelle Kay; Pyxis Regulatory Consulting, Inc.

Shanghai Neway Animal Health Co., Ltd.

Rm 509, 1438 Shan Xi Bei Rd, Shanghai, China, 200060

Tel: 86 21 5187 7909

Fax: 86 21 6148 4508

Website: www.newaypharm.com.cn



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Rita Kumar

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Kevin Sweeney, Senior Entomologist

Date: January 19, 2016

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 428232

Decision no.: 503658

Submission no: 967411

Action code: R315

Product Name: Neove Spot On #001

EPA Reg. No or File Symbol: 91090-G

Formulation Type: Spot-On

Ingredients statement from the label with PC codes included:

Imidacloprid 9.10% PC: 129099

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

For dogs weighing 1.36 to 4.54 kg: 0.014 fl. oz product (96.6 - 322.4 mg product/kg body weight; 8.8 - 29.4 mg imidacloprid/kg body weight)

For dogs weighing 5 to 9.09 kg: 0.034 fl. oz product (120.6 - 219.2 mg product/kg body weight; 11 - 19.98 mg imidacloprid/kg body weight)

For dogs weighing 9.54 to 25 kg: 0.085 fl. oz. product (109.6 - 287.2 mg product/kg body weight; 10 - 26.2 mg imidacloprid/kg body weight)

For dogs weighing over 25 kg: 0.135 fl. oz. product (80.38 - 174.66 mg product/kg body weight; 7.3 - 15.9 mg imidacloprid/kg body weight [note the lower dose range (7.3 mg imidacloprid for this weight class is based on a 54.54 kg dog which is not reflected on the label)])

Use Patterns: Monthly topical treatment for dogs to kill fleas and lice

I. Action Requested: The registrant requests review of five studies to support efficacy claims against fleas and lice for a dog spot-on product containing Imidacloprid.

II. Background: The Agency reviewed the the five submitted MRIDs for several other products (most recent DP 428138) and the reviews below are taken from the previous reviews.

III. MRID Summary:

43679609. Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermally for Control of Fleas on Dogs.

(1) GLP

(2) To test for efficacy against fleas, a 10% imidacloprid spot-on product was applied to dogs at the following rates 0, 3.75 mg, 7.5 mg, and 10.0 mg imidacloprid/kg body weight. Dogs were infested with fleas on days -1, 6, 13, 20, 27, and 33. Fleas were visually counted on days 1, 7, 14, 21, and 28, and on day 34 fleas were combed out of the fur and counted.

(3) **Results:** All imidacloprid treatments killed over 90% of fleas through 34 days post application. Flea survival on control animals was adequate to evaluate efficacy of the imidacloprid treatment.

(4) **Conclusion: Acceptable.** This study supports efficacy claims of kills fleas for up to 34 days (or up to 1 month) at a rate of 3.75 mg imidacloprid/kg body weight for a spot-on product.

43679610. Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermally for Control of Fleas on Dogs.

(1) non-GLP

(2) **Methods:** Thirty-seven adult dogs of various breed and hair lengths were initially selected for the study. On day -2, all 37 dogs were infested with 100 unfed adult fleas. Fleas were combed out, counted, and removed on day -1. Thirty dogs (18 female, 12 male) were chosen to participate in the study on day -1 based on their attractiveness to fleas. Ten dogs were treated with 8.5 mg imidacloprid/kg body weight (8.5% imidacloprid product at 0.1 mL/kg body weight), ten were treated with 10 mg imidacloprid/kg body weight (5.0% imidacloprid product at 0.2 mL/kg body weight) and ten dogs were treated with a placebo control. All treatments were applied directly to the skin. Dogs were infested with 100 adult fleas each on days 6, 13, 20, 27, and 34 (note that the study does not indicate that fleas were inoculated on day -1 or 0). Fleas were counted visually on days 1, 7, 14, 21, and 28, and were combed out and counted on days 35 and 42.

(3) **Results:** Both imidacloprid treatments killed over 90% of fleas through 35 days post treatment. Flea numbers in the control treatment were adequate to evaluate efficacy. Note that the number of fleas per animal was counted on day 1, but the study does not indicate that animals were inoculated with fleas after the comb out on day -1 but before this count. However, 494 total fleas were present on the control animals (49.4 fleas per dog) on day 1 indicating that fleas were inoculated before the day 1 count.

(4) **Conclusion: Partially Acceptable.** This study supports claims of kills fleas for up to 35 days (1 month) post application at a dose of 8.5 mg imidacloprid/kg body weight.

44256901. Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs.

(1) GLP

(2) **Methods:** Thirty dogs were divided into three groups of ten, and dogs in each group received one of the following treatments, 9.1% imidacloprid per label instructions (see table 1 below), 9.7% fipronil per label instructions (see table 2 below), or a placebo control. Dogs were subsequently split into 5 subgroups of two within each treatment. Assuming the formulation density of the proposed product is similar to that of the tested product the rate of imidacloprid tested in the study is the same as the rate on the proposed product. Note the the mean dose tested is 16.75 mg imidacloprid/kg body weight (range of doses tested is approximately 10.9 - 24 mg imidacloprid/kg body weight) if the density assumption is correct. Dogs were infested with 100 adult cat fleas on days -1, 6, 13, 20, and 27. On day 0, fleas were evaluated as live, moribund, or dead on different subgroups of two

dogs from each treatment at each of 2, 4, 8, 12, and 24 h post treatment, and on days 6, 13, 20, and 27 flea evaluations were performed in the same way at the same time intervals post infestation. Live and moribund fleas were collected and held in a separate container for 24 hours to assess mortality.

Table 1. Imidacloprid dosing instructions.

<u>Dog Size</u>	<u>Dose</u>
10 lb and under	0.4 mL
11 - 20 lbs	1.0 mL
21 - 55 lbs.	2.5 mL
Over 55 lbs.	4.0 mL

Table 2. Fipronil dosing instructions.

<u>Dog Size</u>	<u>Dose</u>
up to 22 lbs.	0.67 mL
23 - 44 lbs.	1.34 mL
45 - 88 lbs.	2.68 mL

(3) **Results:** Mortality of fleas exposed to the imidacloprid treatment on dogs for 8 hours or more was over 90% on all evaluation dates except on day 0 and 27. On day 0, mortality of fleas exposed to imidacloprid for 8 hours was 89%, and on day 27 mortality of fleas exposed for 12 hours was 81.5%. However on day 27, mortality of fleas exposed to imidacloprid for 4 hours was 98% and the lower control at 12 hours was the result of increased survival on 1 of the 2 dogs evaluated at 12 hours post infestation. Mortality of fleas exposed to imidacloprid on treated dogs for less than 4 hours did not consistently reach 90% across evaluation dates and replication at each evaluation time point is not adequate for statistical significance. Mortality of fleas exposed to fipronil treated dogs for 8 hours or more was over 90% on all evaluation dates; however, flea mortality when exposed for 2 or 4 hours did not consistently reach 90% across evaluation dates.

(4) **Conclusion: Partially Acceptable.** This study supports claims of kills fleas at the label rate of 16.75 mg imidacloprid/kg body weight for the proposed imidacloprid product because acceptable efficacy was consistently found on at least 6 dogs (the combined sample size of groups with fleas exposed for over 8 hours). However, this study does not support "speed of kill" claims because the sample size of dogs evaluated at each time point (2) was not adequate to show statistical significance of the treatment at any time point. In addition, statistical analyses were not performed. To support "speed of kill" claims, the Agency requires mortality in the treated group to be significantly different from mortality in the control group at the desired time point after statistical analysis.

44256902. Imidacloprid Topical Formulation Larvacidal Effect Against *Ctenocephalides felis* in the Surroundings of Treated Dogs.

(1) non-GLP

(2) **Methods/Results:** This MRID contains two studies, one which used only four dogs for testing, and a second study which used seven dogs split into two groups. Because neither study was adequately replicated, this study was not evaluated further.

(3) **Conclusion: Unacceptable.** Neither study in this MRID was replicated adequately. The Agency recommends a minimum of six animals per treatment group for sufficient replication and statistical power.

4426903. Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs.

(1) GLP

(2) **Methods:** Twenty four dogs were divided into three groups. Two groups (1, 2) were treated with a 9.1% imidacloprid spot-on product (**Group 1:** dose range: 11.0-25.5 mg imidacloprid/kg body weight, Average dose: 16.1 mg imidacloprid/kg body weight; **Group 2:** Dose range: 11.4-17.8 mg imidacloprid/kg body weight, Average dose: 14.5 mg imidacloprid/kg body weight) and group 3 served as the untreated control group. Dogs were infested with 100 adult fleas on days -1, 6, 13, 20, 27, and 34. Live fleas were counted and removed from the dog on days 1, 7, 14, 21, 28, and 35. On day 4, all dogs in group 1 and 4 dogs from group 3 were shampooed and rinsed, and all dogs in group 2 and 4 dogs from group 3 were immersed in a tank of water for one minute. During the one minute immersion period, the study staff dunked the dogs heads under water three times. All dogs immersed in water on day 4 were also immersed in the same manner on days 11, 18, 25 and 32.

(3) **Results:** Over 90% mortality of fleas on dogs in group 1 was observed through day 28. On day 35, flea mortality only reached 65.5% on dogs in group 1. Mortality of fleas on dogs in group 2 was over 90% through 14 days post treatment, 89.7% on day 21, 88.8% on day 28, and 78.7% on day 35.

(4) **Conclusion: Partially Acceptable.** This study supports claims of kills fleas at the dose rate of 16.1 mg imidacloprid/kg body weight because efficacy in group 1 was over 90% through 28 days post application. This study does not support claims of "water resistant" or "effective after bathing/shampooing" because the tests for these claims need to be more rigorous. For the "water resistant" and shampooing/bathing related claims, the Agency requires a test that includes shampooing animals and then rinsing for 5 minutes.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data support efficacy claims of kills fleas at a minimum rate of 3.75 mg imidacloprid/kg body weight for the proposed product.

The submitted data also do not support claims of "water resistant" or "speed of kill" types of claims for the proposed product.

V. LABEL RECOMMENDATIONS:

(1) Make the following changes to the Directions for Use:

On page 7 under Product Information:

The first paragraph should be changed to read: "Feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [product name] kills fleas which may cause this condition."

Delete the second paragraph: "[Product name] kills fleas on dogs...depending on climatic conditions."

Modify the third paragraph to read: "Larval flea stages are killed following contact with [product name] treated dogs."

Delete the fourth paragraph: "[Product name] is waterproof...rain or sunlight."

The fifth paragraph regarding "Monthly treatments are required for optimal control and prevention of fleas." is acceptable as written.

(2) The following marketing claims are acceptable, note claims followed with an asterisk are modified from those found on the current label:

Kills fleas

One treatment prevents further flea infestation for at least four weeks

Kills [biting, chewing] lice

For treatment and prevention of [biting, chewing] lice [infestations]

Controls existing [biting, chewing] lice infestations

*Dual protection against fleas and lice

Treats, prevents and controls [biting, chewing] lice [infestations]

Provides effective control of [biting, chewing] lice [infestations]

Kills [biting, chewing] lice and prevents further infestations

For treatment and prevention of infestations with [biting, chewing] lice

(3) The following marketing claims are unacceptable:

Kills fleas on dogs within 12 hours

Kills fleas before they lay eggs

(4) The following MRIDs should be removed from the data matrix, because they are classified as "unacceptable" to support the product: 44256902

(5) Note to PM/Reviewer: Although MRID 43679609 shows efficacy of imidacloprid rates of 3.75 and 7.5 mg imidacloprid/kg body weight, for consistent dosing across weight classes, we suggest adding another weight class and application volume to the label because the dosing in the over 25 kg weight class is lower for large dogs (over 80-85 lb) than the other weight classes. In addition the submitted studies did not test the spot-on product on large dogs, so we do not know how the application volume will affect efficacy on large dogs. The weight classes below would be appropriate:

56 – 80 or 85 lb dogs at the 0.135 fl. oz. (4 ml) volume

80 or 85 lb dogs and over at a higher volume

Kumar, Rita

Resubmission!
S 981466

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Thursday, December 24, 2015 3:37 PM
To: Kumar, Rita
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G
Attachments: 91090-G.20151224.Shanghai Neove Spot on label_revised.pdf

Rita,

No problem, the revised label is attached. I put the eye warning in the use restrictions section because it seemed more obvious but if you think it is more appropriate in the Hazards to Domestic Animals section, let me know and I can move it. In the meantime, I hope you have a wonderful Holiday.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Kumar, Rita [mailto:Kumar.Rita@epa.gov]
Sent: Monday, December 14, 2015 1:28 PM
To: Janelle Kay <Janelle@PyxisRC.com>
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Dear Janelle: The CRP requirement is not applicable. Please note that in addition to changing the Signal Word to Warning, you must also add the following text to precautionary statements: "Wash hands after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet." Also, the label must state that the product must not get in cat's (or dog's?) eyes.

Regards,
Rita

From: Janelle Kay [mailto:Janelle@PyxisRC.com]
Sent: Monday, December 14, 2015 1:57 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Dear Rita,

I wanted to confirm that you received our response last week. Also, attached is a revised label correcting the signal word (I also corrected the country of origin). Please let me know if you have any questions, need any additional information, or submit the response formally through the front end. In the meantime, I hope you and your family have a wonderful Holiday season!

MASTER LABEL

[Front Panel]

Neove Spot On #001**Alternate Brand Names**

ImidaCare for Dogs [& or Puppies]

ImidaStar for Dogs [& or Puppies]

PetImida for Dogs [& or Puppies]

Once a Month Topical Flea and Lice Treatment

For Use Only on **Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs****OR****Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs****OR****Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs****OR****Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs****READ THE ENTIRE LABEL BEFORE EACH USE**

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- One treatment prevents further flea infestation for at least four weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [biting, chewing] lice
- For treatment and prevention of [biting, chewing] lice [infestations]
- Controls existing [biting, chewing] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [biting, chewing] lice [infestations]
- Provides effective control of [biting, chewing] lice [infestations]
- Kills [biting, chewing] lice and prevents further infestations
- For treatment and prevention of infestations with [biting, chewing] lice
- Waterproof
- Fragrance free

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0
EPA Est. No. 091090-XXX-X	EPA Reg. No. 091090 -XXX

KEEP OUT OF REACH OF CHILDREN
WARNING

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.



Icon size 1.5cm x 1.5cm

[Back Panel]

Once a Month Topical Flea and Lice Treatment
 For Use Only on **Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs**
OR
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS**

WARNING Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Keep out of reach of children. Do not contaminate feed or food.

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
To Physician: Treat the patient symptomatically.	

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

Side Effects Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



Icon size 1.5cm x 1.5cm

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing 3½ - 10 lbs.
OR
11 - 20 lbs
OR
21 - 55 lbs
OR
Over 55 lbs
- Do not use on other animals.
- Do not apply to puppies or dogs weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.
- Do allow the product in the dog's eyes.

Net Contents: [X] Tube(s) each 0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

Manufactured For

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

[Made in China]

[Back Panel and/or Insert]

Once a Month Topical Flea and Lice Treatment
For Use Only on **Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs**
OR
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as show. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.

Visuals depicting how to open blister pack

3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN BLISTER PACK"
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.

Visuals depicting Application to Animal

4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every

seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

Larval flea stages in the dog's surroundings are killed following contact with [Product Name] treated dogs.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container.

If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

[Label on Individual Tube]

[Neove Spot On #001]

9.1% Imidacloprid

0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 091090-XXX

WARNING

Keep Out of Reach of Children
Read the Entire Label before Use

[NEWAY]

Lot No. 0000000

Kumar, Rita

From: Kumar, Rita
Sent: Monday, December 14, 2015 4:28 PM
To: 'Janelle Kay'
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Dear Janelle: The CRP requirement is not applicable. Please note that in addition to changing the Signal Word to Warning, you must also add the following text to precautionary statements: Wash hands after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet." Also, the label must state that the product must not get in cat's (or dog's?) eyes.

Regards,
Rita

From: Janelle Kay [mailto:Janelle@PyxisRC.com]
Sent: Monday, December 14, 2015 1:57 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Dear Rita,

I wanted to confirm that you received our response last week. Also, attached is a revised label correcting the signal word (I also corrected the country of origin). Please let me know if you have any questions, need any additional information, or submit the response formally through the front end. In the meantime, I hope you and your family have a wonderful Holiday season!

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Janelle Kay
Sent: Monday, December 07, 2015 3:59 PM
To: 'Kumar, Rita' <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Dear Rita,

Thank you for your email. With respect to the labeling, we agree that the signal word needs to be revised in order to reflect the toxicity categories determined in the review. With respect to the precautionary statements, perhaps we can discuss this further? I agree that the language on the submitted label is not consistent verbatim with the Label Review

Manual. However, with the exception of the signal word which we agree to change, the precautionary language on the proposed label is similar, if not identical, to the language on the substantially similar product (EPA Reg. No. 11556-117, 119, 120 and 122). We believe that requiring Shanghai Newway to modify its label in a manner that is different than the competitor products could not only pose a misuse of the product, but could put Shanghai Newway in a significant competitive disadvantage, in an already competitive marketplace. If the Agency is willing to consider only a signal word change, then we can promptly submit a revised label reflecting the correct signal word.

With respect to the CRP requirement, it would be helpful if you sent the review indicating that these data are required. You've stated that based on the eye irritation that CRP is required. However, based on the reviews of the data cited by Shanghai Newway (http://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-129099_5-Mar-96_094.pdf), the substantially similar product has the following toxicity profile (this is consistent with the toxicity category you identified below):

Acute Oral	III	LD50 1838 mg/kg
Acute Dermal	III	LD50 > 2000 mg/kg
Acute Inhalation	IV	LC50 > 2.415 mg/L
Primary Dermal	IV	Mild erythema in one animal at 24 hours, cleared by 48 hours.
Primary Eye	II	Corneal opacity, iritis, conjunctival redness and chemosis, and ocular

discharged in one or more animals. All signs resolved within 14 days.

Dermal Sensitization	Non Sensitizer
----------------------	----------------

Based on the CRP criteria under 40 CFR 157.22, I think we both agree that acute oral, acute dermal, acute inhalation, or primary dermal routes of exposure do not trigger CRP. However, under 40 CFR 157.22(a)(4), the criteria for eye irritation is that the product must be corrosive or causes corneal involvement/irritation persisting for 21 days or more. According to the label review manual toxicity classifications (Chapter 7, Table 1, page 7-2; July 2014), a product that is corrosive or causes corneal involvement/irritation persisting for 21 days or more would be classified as a Toxicity Category I, not II, for eye irritation. Given that the proposed product is a Tox. Cat. II for eye irritation, I don't understand how this product triggers CRP.

I would appreciate your input on the CRP and precautionary language issues I raised above. I'm in the office all week if you would like to discuss further. In the meantime, please let me know if you have any questions or need any additional information.

Regards,

Janelle

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(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Kumar, Rita [<mailto:Kumar.Rita@epa.gov>]
Sent: Friday, December 04, 2015 7:42 AM
To: Janelle Kay <Janelle@PyxisRC.com>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: Pending application for Neove Spot On #001; EPA File symbol 91090-G
Importance: High

Dear Janelle: This application is currently in review. However, we need you to address the following deficiencies:

1. Based on the cited acute toxicity studies, the following acute toxicity categories have been assigned to this product:

Acute Oral	III
Acute Dermal	III
Acute Inhalation	IV
Primary Dermal	IV
Primary Eye	II
Dermal Sensitization	Non Sensitizer

The precautionary statements must be revised according to these tox categories.

2. Based on the eye irritation category, this product must be in child resistant packaging (CRP). A child resistant certification is required. Please submit one.

Please respond within 10 days indicating how soon you will submit the revised label and CRP certification.

Regards,

Rita

Kumar, Rita

From: Eagle, Venus
Sent: Monday, December 14, 2015 3:48 PM
To: Kumar, Rita
Subject: RE: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Agreed as long as the language on the label directs use away from the user and pets eyes. Note that we are going back to Bayer to update the precautionary language as we discussed so please make sure they update their labels today's standards.

Venus Eagle
Product Manager 1
Invertebrate & Vertebrate Branch 3
Registration Division, Office of Pesticide Programs
US EPA (Mail Code 7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Phone: 703.308.8045

From: Kumar, Rita
Sent: Monday, December 14, 2015 2:10 PM
To: Eagle, Venus <Eagle.Venus@epa.gov>
Subject: FW: Pending application for Neove Spot On #001; EPA File symbol 91090-G

Venus: I talked to you about this last week also. Just wanted to confirm that the registrant does not need to submit CRP for the following reasons:

1. Tox category II for eye irritation does not trigger CRP.
2. They cited Bayer data, and Bayer products (9.1% imidacloprid) are not in CRP.

Please confirm this so that I can inform Janelle.

Thanks,
Rita

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Monday, December 14, 2015 1:57 PM
To: Kumar, Rita <Kumar.Rita@epa.gov>
Cc: Eagle, Venus <Eagle.Venus@epa.gov>
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Cc: Eagle, Venus <Eagle.Venus@epa.gov>
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5981453

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Dermal Sensitization Non Sensitizer

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Regards,

Janelle

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Importance: High

Dear Janelle: This application is currently in review. However, we need you to address the following deficiencies:

1. Based on the cited acute toxicity studies, the following acute toxicity categories have been assigned to this product:

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2. Based on the eye irritation category, this product must be in child resistant packaging (CRP). A child resistant certification is required. Please submit one.

Please respond within 10 days indicating how soon you will submit the revised label and CRP certification.

Regards,
Rita



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

DP BAR CODE NO.: 428230
PC Code: 129099
FOOD Use: No

EPA File Symbol NO.: 91090-G
ACTION CODE: R315

DECISION NO.: 503658

DATE OUT: 11/19/ 2015

SUBJECT: End Use Product Chemistry Review
Product Name: Neove Spot On #001

FROM: Hari Mukhoty, DVM, PhD.
Product Chemistry Team
CITAB / Registration Division (7505P)

TO: Rita Kumar, RMR / Venus Eagle, RM 01
Invertebrate & Vertebrate Branch 3 / Registration Division (7505P)

Company Name: Shanghai Newway Animal Health Co., Ltd
Formulation Type: Not Provided

INTRODUCTION:

The registrant has submitted an updated basic CSF (Dated: 11/23/2015) and has proposed a product specific label for registration of the aforesaid product under EPA File Symbol No. 91090-G.

The product chemistry Group A and Group B data have been submitted under MRIDs: 496214-01, -02 & -03 and data matrix dated 06/10/2015. Self-Certification Statement (Dated 11/20/2015) have also been submitted.

The aforesaid basic end-use product is manufactured by Shanghai Newway Animal Health Co., China.

CITAB has been requested to evaluate the product chemistry data required for registration of the proposed formulation.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Imidacloprid (9.1%).
2. Has the registrant claimed substantial similarity to registered product?
[] Yes [X] No [] NA If yes: EPA Reg. No.
3. The source material of the active ingredient is registered with the Agency [Yes].
4. The CSF has been screened by inert group and they found that inerts are approved for food use.

DP BAR CODE NO.: 428230
PC Code: 129099
FOOD Use: No

EPA File Symbol NO.: 91090-G
ACTION CODE: R315

DECISION NO.: 503658

5. Confidential Statement of Formula(s):

☒ Basic -
☐ Alternate -

Dated: 04/15/2015
Dated:

Re-submitted: 11/23/2015
Re-submitted: NA

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐

6. Product label

a. Ingredient statement: Nominal concentrations of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☐ Yes ☐ No - There was no proposed label with the package. Therefore, this cannot be evaluated.

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"

, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid equivalent: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☒ No ☐ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 428230
PC Code: 129099
FOOD Use: No

EPA File Symbol NO.: 91090-G
ACTION CODE: R315

DECISION NO.: 503658

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	496214-01
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X	"	A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			NR	NR	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method #		X		A	496214-01

A = Acceptance, NR = Not Required, G = Data Gap,

W = Waiver Request, I = In Progress, NA = Not Acceptable

Analytical Method: Capillary GC - FID was used. Method validation data for linearity, accuracy and precision have been submitted.

DP BAR CODE NO.: 428230
PC Code: 129099
FOOD Use: No

EPA File Symbol NO.: 91090-G
ACTION CODE: R315

DECISION NO.: 503658

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	496214-02
830.6314	Oxidation/reduction	Incompatible with 5% potassium permanganate. Compatible with other ingredients.	A	Self-Certified / NW-PO3-E02
830.6315	Flammability	Flash point 215° F		"
830.6316	Explodability	Product does not have chemical bonds or functional groups associated with explosive chemicals.	A	Requested waiver
830.6317	Storage stability	At 54° C for 14 days did not fall below lower citified limits. Stable	A	496124-03 / Self Certified / 49621403
830.6310	Miscibility	NA / petroleum solvent is not to be used	A	496160-02
830.6320	Corrosion characteristics	At 54° C for 14 days / No signs of corrosion were visible.		496124-03
830.7000	pH	Product is neutral in pH 7.2		NW-P03-E02
830.7100	Viscosity	6.153 mPa	A	496214-02
830.7300	Density	1.098 g/ml	A	"
830.7520	Particle size	NA / Product is water soluble liquid.	NA	"

A = Acceptable, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress

DP BAR CODE NO.: 428230
PC Code: 129099
FOOD Use: No

EPA File Symbol NO.: 91090-G
ACTION CODE: R315

DECISION NO.: 503658

CONCLUSIONS:

1. CITAB has reviewed the CSF (Dated: 11/23/2015) for the proposed basic and finds it to be acceptable. The CSF is attached with this review and can be located in OPPIN CHEM DOCS.
2. Product chemistry Group A data and Group B data are satisfied and acceptable.
3. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

Companion Animals Safety

August 19, 2015

MEMORANDUM

Subject: Name of Pesticide Product: NEOVE SPOT ON #001
EPA Reg. No. /File Symbol: 91090-G
DP Barcode: DP 428231
Decision No.: 503658
Action Code: R315
E-Sub#: --
PC Code: 129099 (Imidacloprid: 9.1%)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

Byron T. Backus
Aug - 19 - 2015

Through: John Redden, M.S., Senior Risk Assessor
CITAB
Registration Division (7505P)

JCR

To: Rita Kumar/Venus Eagle RM 01
IVB3
Registration Division (7505P)

Registrant: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	by wt.
129099 Imidacloprid	9.1%
<u>Other Ingredient(s):</u>	90.9%
TOTAL	100.0%

ACTION REQUESTED: The Risk Manager requests:

"CITAB/Companion animal team: Please provide a technical screen and full review of cited companion animal safety studies cited to support registration of this dog spot-on product. Copies of cover letter, data matrix, and proposed label are provided..."

BACKGROUND: In the cover letter dated April 17, 2015 the registrant's representative has stated that: "A receipt for the PRIA-3 category R-301 payment is attached" (this is actually an R315 action) and that "The following documents are enclosed to support the tolerance exemption for this petition:" (no tolerance exemptions are required for this proposed dog spot-on).

From the proposed label for EPA File Symbol 91090-G, doses are 0.4 mL (0.014 fl. oz.) for dogs weighing 3½ to 10 lbs, 1.0 mL (0.034 fl. oz.) for dogs weighing 11-20 lbs, 2.5 mL (0.084 fl. oz.) for dogs weighing 21-55 lbs, and 4.0 mL (0.135 fl. oz.) for dogs weighing more than 55 lbs.

According to the data matrix (dated June 10, 2015) for EPA File Symbol 91090-G the registrant has cited the following studies to satisfy the companion animal safety data requirements for this product: MRIDs 43679607, 43679308 [Note: this should be 43679608], 44099801, and 44179801.

PREVIOUS REVIEWS:

1. The study in MRID 43679607 was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

Nine adult dogs of mixed breed (3 males, 6 females, one male and two females/group) were dermally exposed to Imidacloprid, 10% Spot-On. Dose levels were 50 mg/kg/day x 1 day, and 50 mg/kg/day x 3 days. Controls received placebo (formulation less active ingredient) at 50 mg/kg/day x 3 days.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg without significant reactions.

This...study is classified as Acceptable when combined with another study, and satisfies the requirement for a domestic animal study in the dog, 18 lb (8 kg) body weight and above. The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the dog (MRID 43679608), the information is considered useful.

2. The study in MRID 43679608 [not 43679308] was reviewed in HED (TXR 0011821, sign-off date 03/05/96) with the following summary:

18 adult dogs of various breeds (3 males and 3 females/group) were dermally exposed to Imidacloprid, 10% Spot-On formulation at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50 mg/kg.

No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg of the active ingredient without significant reactions. Inadequate testing was done in dogs less than four months old.

This repeated dose dermal study is classified as Acceptable and satisfies the requirements for a General Safety Evaluation for Topical Use (86-1) in the dog.

3. The study in MRID 44099801 was reviewed in HED (TXR 0012322, sign-off date 09/24/97) with the following summary:

In a domestic animal safety study (MRID #44099801), six 7 week-old puppies/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 mL if < 10 lbs; 5.0 mL if > 10 lbs) at weekly intervals for eight treatments. Six puppies/sex were treated with the vehicle control at the recommended use rate (0.4 mL if < 10 lbs; 1.0 mL if > 10 lbs) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 7 week-old puppies can tolerate a dose of 5X the recommended use rate.

The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.

4. There is no record of a review for the study in MRID 44179801 [Shmidl, J.; Arther, R. (1996) Acute Oral Toxicity Evaluation of Imidacloprid (Advantage) in Dogs: Lab Project Number: TR-96D-010: 74764: J:\USERS\LINDA\NOREPORT\JAS0171.RPT. Unpublished study prepared by Bayer Corp., Animal Health. 10 p.]. The following is a summary of that study:

The study was conducted to evaluate the acute toxicity of the formulation and the formulation minus the active ingredient (placebo) when administered orally at the topical use rate. The labeled use rate is 1.0 mL for dogs weighing 11 to 20 lb; 2.5 mL for 21 to 55 lb and 5.0 mL for dogs weighing > 55 lb. Group 1 dogs received a single treatment of placebo (formulation minus the active ingredient) equivalent to use rate volume. Group 2 dogs received a single treatment of the formulation at the use rate volume.

The treatment volumes were placed in gelatin capsules and administered directly in the throat area. The gelatin capsules were swallowed intact.

Two dogs in Group 2 vomited at approximately one hour following treatment. None of the remaining 10 dogs had any clinical signs.

The purpose and protocol of this study are inconsistent with the 870.7200 Guidelines. This study, while providing relevant information, does not satisfy the 870.7200 data requirements.

5. The study in MRID 44099801 does not support a minimum weight of 3½ lbs. From Table 2 (p. 9 of MRID 44099801) the initial weights of the 6 male puppies ranged from 1.8 to 3.0 kg, and the initial weights of the 6 female puppies ranged from 1.5 to 2.1 kg. The mean weight of the 4 lowest weight male puppies (1.8, 1.8, 2.3 and 2.5 kg) and the four lowest weight female puppies (1.5, 1.7, 1.8 and 1.8 kg) was 1.9 (± a standard deviation of 0.33) kg, equal to 4.19 (± 0.73) lbs. This study supports a minimum weight of 4 lbs (1.81 kg), not 3½ lbs (1.59 kg), and the label must be revised accordingly.

6. From p. 4 of MRID 44099801 the puppies had birthdates of March 16, 1996 through March 19, 1996. From p. 5 the first treatment was on May 3, 1996, so the puppies were from 45 to 48 days old on that date. This study supports a minimum age of 7 weeks, as proposed by the registrant.
7. With the revision of minimum weight from 3½ to 4 lbs, the companion animal safety (870.7200) data requirements for the registration of 91090-G have been satisfied.
8. The registrant should revise the citation of MRID 43679308 to 43679608.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D428230; FILE SYMBOL No.: 91090-G (screen); PRODUCT NAME: NEOVE Spot On #001; DECISION No.: 503658; PC Code(s): 129099; ACTION CODE: R315; FOOD Use: Yes

DATE OUT: July 27, 2015

SUBJECT: Completeness check screening for end use product "NEOVE Spot On #1"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB / RD (7505P)

TO: Rita Kumar / Venus Eagle, RM 01
I-V Branch 3 / RD (7505P)

Company Name: Shanghai Newway Animal Health Co., Ltd.
Formulation Type: Insecticide
Active Ingredient(s): Imidacloprid (9.10%)
MRID Nos: 49621401 to 49621403

CONCLUSION:

Deficiencies: Yes

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All required data submitted or requested waiver, except for the guideline 830.7000 (pH).

Note 1: The registrant must submit data on this guideline. The Data Matrix has indicated the inclusion of this guideline under MRID 49621402, but no data was found. The registrant must submit this study.

Note 2: The registrant has requested waivers in Data Matrix (dated June 10, 2015) for numbers of group B data but no justifications have been provided for waiver requests. The registrant must submit proper justifications for waiver requests.

CSF: Basic CSF (dated 04-15-2015) submitted.

Note 3: The CSF has been submitted incorrectly and must be revised. The nominal concentration of the AI in the proposed product must be calculated based on the percent purity of the AI [REDACTED] in the source product [REDACTED]. The amounts of other ingredients must be adjusted accordingly.

Product Draft Label: Submitted.

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

~~CONTAINS CBI - DO NOT RELEASE TO REGISTRANT~~

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 91090-G/Neove Spot On #001
DP Barcode: 427278
PC Code: 129099

From: Marianne Lewis, Biologist
Invertebrate Vertebrate Branch 3
Registration Division (7505P)

To: Venus Eagle, PM 01
Invertebrate Vertebrate Branch 3
Registration Division (7505P)

Applicant: Shanghai Neway Animal Health Co., Ltd
Rm 509, 1438 Shan Xi Bei Rd
Shanghai, China, 200060.

Marianne Lewis
scr *5/13/15*

FORMULATION FROM EPA Reg. No. 91090-G LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Imidacloprid:	9.1%
<u>Inert Ingredient(s):</u>	90.9%
Total	100.0%

BACKGROUND: The registrant is claiming substantial-similarity to EPA Reg. No. 11556-117 to support the registration of their new product, EPA Reg. No. 91090-G. After comparing the CSF from the subject product and EPA Reg. No. 11556-117, it has been determined that the products are substantially similar. The following acute toxicity categories will be assigned to the subject product: acute oral (81-1) – III; acute dermal (81-2) – III; acute inhalation (81-3) – IV; primary eye irritation (81-4) – II; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer (81-6).

Note to PM/Reviewer: The registrant cited acute toxicity studies (450969-04 through -09) in their data matrix. However, these studies were conducted with EPA Reg. No. 11556-125 which is not similar to the subject product. Since the subject product is identical to EPA Reg. No. 11556-117, which has acceptable toxicity studies from when it was registered (HED 3/5/96), the same toxicity categories were assigned to the product.

RECOMMENDATIONS:

- The subject product will be assigned the Toxicity Categories listed above.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 91090-G is currently:

Acute Oral	III
Acute Dermal	III
Acute Inhalation	IV
Primary Eye	II
Primary Dermal	IV
Skin sensitization	non sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 091090-G NEOVE SPOT ON #001

RESTRICTED USE LABELING:

Based on primary eye irritation Toxicity Category II – residential use

SIGNAL WORD: **WARNING** **AVISO**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Causes substantial but temporary eye injury. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles, safety glasses, face shield), long sleeved shirt, long pants, shoes, socks and chemical resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton, selection category C).

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Kumar, Rita

From: Bohnenblust, Eric
Sent: Tuesday, August 25, 2015 2:40 PM
To: Kumar, Rita
Subject: RE: Need to know the status of technical screen of cited efficacy data for 91090-G

It passed.

From: Kumar, Rita
Sent: Tuesday, August 25, 2015 2:32 PM
To: Bohnenblust, Eric
Subject: Need to know the status of technical screen of cited efficacy data for 91090-G
Importance: High

Eric: This was beaned to efficacy on 7/17, and I requested a technical screen by 7/31. Can you please tell me status of this screen?

Decision: 503658
DP: 428232

Thanks,
Rita

Revised data matrix for ~~11556-117~~ 91090-G atiny 11556-117 as me-too registered 10/25/14

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Need to check [redacted] to ensure companion animal okay

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DATA MATRIX

Date June 10, 2015

EPA Reg. No./File Symbol 91090-G

Page 1 of 4

Applicant's/Registrant's Name & Address

Shanghai Neway Animal Health Co.
Rm 509, 1438 Shang Xi Bei Rd.
Shanghai 200060, China

Product

Neove Spot On #001

Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)

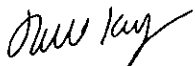
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.1600	Description of Materials Used to Produce the Product	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.1670	Discussion of Formation of Impurities	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.1800	Enforcement Analytical Method	49621401 ✓	Shanghai Neway Animal Health Co.	OWN	
830.6302	Color	49621402 ✓	Shanghai Neway Animal Health Co.	OWN	
830.6303	Physical State	49621402 ✓	Shanghai Neway Animal Health Co.	OWN	
Signature <i>Janelle Kay</i>			Name and Title Janelle Kay, Agent		Date June 10, 2015

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DATA MATRIX

Date June 10, 2015			EPA Reg. No./File Symbol 91090-G		Page 2 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China			Product Neove Spot On #001		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	49621402 ✓	Shanghai Neway Animal Health Co.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility				Waiver
830.6315	Flammability				Waiver
830.6316	Explosibility				Waiver
830.6317	Storage Stability	49621403 ✓	Shanghai Neway Animal Health Co.	OWN	
830.6319	Miscibility				Not required ⁴
830.6320	Corrosion Characteristics	49621403 ✓	Shanghai Neway Animal Health Co.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	49621402 ✓	Shanghai Neway Animal Health Co.	OWN	
830.7050	UV/Visible Absorption				Not required ⁶
830.7100	Viscosity	49621402 ✓	Shanghai Neway Animal Health Co.	OWN	
830.7200	Melting Point/Melting Range				Not required ⁶
Signature 			Name and Title Janelle Kay, Agent		Date June 10, 2015

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DATA MATRIX

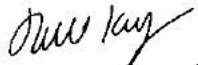
Date June 10, 2015			EPA Reg. No./File Symbol 91090-G		Page 3 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China			Product Neove Spot On #001		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Point/Boiling Range				Not required ⁶
830.7300	Density/Relative Density/Bulk Density	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7370	Dissociation Constants in Water				Not required ⁶
830.7520	Particle size, fiber length, diameter distribution				Not required
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁶
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁶
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁶
870.1100	Acute Oral Toxicity: Rat	43679601	June 7, 1995	OLD	Waiver
870.1200	Acute Dermal Toxicity: Rat	43679602	19 yrs.	OLD	Waiver
870.1300	Acute Inhalation Toxicity: Rat	43679603	19 yrs.	OLD	Waiver
Signature <i>Janelle Kay</i>			Name and Title Janelle Kay, Agent		Date June 10, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date June 10, 2015		EPA Reg. No./File Symbol 91090-G		Page 4 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China		Product Neove Spot On #001			
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation: Rabbit	43679604	7 yrs. old	OLD	
870.2500	Primary Dermal Irritation	43679605		OLD	
870.2600	Dermal Sensitization	43679606		OLD	
870.7200	Companion Animal Safety	43679607	Dogs	OLD	
		43679608	Dogs	OLD	
		44099801	Puppies Aug.	OLD	
		44179801	Puppies	OLD	
810.3300	Product Performance	43679609	Dogs		
		43679610	Dogs		
		44256901	speed of flea kill 7 yrs. old		
		44256902	Larvicidal eff.		
		44256903	Effect on shampooing		
Generic Data Requirements		Missing 47109101	7 yrs. old		
Neove Spot On #001 qualifies for the Formulator's Exemption for imidacloprid generic data requirements.		47298201	8 yrs. old		
Signature 		Name and Title Janelle Kay, Agent		Date June 10, 2015	

Endnotes for Neove Spot On #001

- ¹ **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- ² **830.1700** - This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- ³ **830.6313** - These data are not required for registration of an end-use product.
- ⁴ **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Neove Spot On #001 is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- ⁵ **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- ⁶ **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** - These data are not required for registration of an end-use product.

Cc: Eagle, Venus
Subject: RE: EPA File Symbol 91090-G

Hi Janelle,

That letter is generated with the recode. We don't want to recode it and invoice the applicant until we have indication this is the preferred course of action, as should your client choose to withdraw they would be allowed to do so under the current R301 category instead of R315. But the outstanding balance would be the R315 fee minus the R301 fee. My quick calculation is that it would be \$6,594?

Best regards, Steve

Stephen A. Schaible, PRIA Ombudsman
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]
Sent: Tuesday, June 23, 2015 1:25 PM
To: Schaible, Stephen
Cc: Eagle, Venus
Subject: RE: EPA File Symbol 91090-G

Steve,

Thanks for the information; I'll convey this to Shanghai Neway. Do you have a letter/invoice to reflect the additional payment due?

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Schaible, Stephen [<mailto:Schaible.Stephen@epa.gov>]
Sent: Friday, June 19, 2015 11:41 AM
To: Janelle Kay
Cc: Eagle, Venus
Subject: RE: EPA File Symbol 91090-G

Hi Janelle,

Schaible, Stephen

From: Schaible, Stephen
Sent: Friday, June 26, 2015 10:17 AM
To: Yanchulis, Michael
Cc: Eagle, Venus; 'Janelle@PyxisRC.com'
Subject: EPA File Symbol 91090-G (D503658)- Recode from R301 to R315
Attachments: 20150520 Fee Waiver Approval Letter.pdf

Hi Mick,

For the reasons listed in the email thread below (my email dated 6/19), please recode EPA File Symbol 91090-G (D503658) from the current R301 category to R315 and invoice Pyxis (agent for Shanghai Neway) for the outstanding balance. Please note that a 75% small business waiver was requested and has been granted (see attached). Per Janelle Kay's email below, the client does wish to proceed with review of the application under the R315 category.

Thanks! Steve

Stephen A. Schaible, PRIA Ombudsman
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362

From: Janelle Kay [mailto:Janelle@PyxisRC.com]
Sent: Wednesday, June 24, 2015 6:23 PM
To: Schaible, Stephen
Cc: Eagle, Venus
Subject: RE: EPA File Symbol 91090-G

Steve,

Shanghai Neway has decide to proceed with the reclassification, so please send me the invoice. Note: they did get approved for a small business reduction, so I'm not sure if the invoice will reflect that amount or if I should do the calculation when I pay.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

From: Schaible, Stephen [mailto:Schaible.Stephen@epa.gov]
Sent: Tuesday, June 23, 2015 10:29 AM
To: Janelle Kay

Sorry for the delay in getting back to you sooner. Venus and I have looked through this application, doing a preliminary screen of the elements of the package. It is our conclusion that the R315 category is applicable rather than the requested R301 for the following reasons:

- Not 100% identical based on a CSF comparison with the cited product, though similar within the certified limits (not itself a reason for recode).
- Data matrix for proposed product (91090-G) does not cite all of the same CASS studies as those listed on the cited substantially similar products (of which there are 4):
 - 11556-117 (this is the product that is nearly identical)
 - 11556-119
 - 11556-120
 - 11556-122
- Claims being made on the proposed label do not match the claims on the cited substantially similar product(s).

For these reasons, the review necessary to make a decision on this application falls outside of the scope contemplated for the "me-too" R301 category. I'm happy to discuss this on the phone if you would like. This issue was taken to the RD PRIA Managers meeting last week and the above conclusion was supported. This determination is consistent with how EPA has been coding pet spot-on products with this approach to data citation. The R301 application for a pet spot on product would have to be 100% identical in composition and have the same claims as the cited product, and cite the same studies as the cited product. Those conditions are not met in this situation.

Best regards, Steve

Stephen A. Schaible, PRIA Ombudsman
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362

From: Janelle Kay [<mailto:Janelle@PyxisRC.com>]

Sent: Wednesday, June 10, 2015 6:05 PM

To: Schaible, Stephen

Cc: Eagle, Venus

Subject: EPA File Symbol 91090-G

Steve/Venus,

I hope all is well with both of you. I understand you've been in communication with Jim Yowell regarding a pending application for Shanghai Neway (EPA File Symbol 91090-G) for a product called Neove Spot On #001. Shanghai Neway has decided to change agents to Pyxis for this product (not for the company) and I've provided a copy of the LOA attached.

First, I understand there were some deficiencies with the data matrix (i.e. failure to cite target animal safety data) and it appears there were also inconsistencies between the citations and the Certification with Respect to Citation of Data. I have corrected these errors in the attached matrices (Agency and Public) and certification.

Second, I understand there are some concerns regarding the PRIA category. Specifically, Shanghai Neway believes that its product is identical to Bayer Healthcare's Advantage 10 Topical Solution (EPA Reg. No. 11556-117) (and related products 11556-119, -120, 122). It has also not submitted any acute toxicity, efficacy or safety data with its application and, based on the formulation and data submitted, we believe R301 is the more appropriate PRIA category. To be clear, Shanghai Neway does not want to withdraw its application but would like additional information from EPA as to why it

has decided (if it still does believe that) the application should be classified as R315. I apologize in advance if you have already addressed this issue with Mr. Yowell (and for any other complications as a result of the agent change).

I look forward to hearing from you. In the meantime, please let me know if you have any questions or need any additional information.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

Eagle, Venus

From: Schaible, Stephen
Sent: Tuesday, June 02, 2015 9:52 AM
To: James Yowell
Cc: Eagle, Venus
Subject: EPA File Symbol 91090-G

Hi Jim,

Per our telephone conversation, your application for the new dog spot-on product Neove Spot On #001, EPA File Symbol 91090-G, is deficient in that it does not address data requirement for the companion animal safety studies. Please submit to Venus Eagle a revised data matrix and (if necessary) certification with respect to citation of data form indicating how you wish to address this data requirement.

In addition, as this is a pet-spot on product, the appropriate PRIA category for this action is R315 (decision review time frame of 9 months, \$8,400). Your client has the choice of continuing the review under this category or withdrawing the application under the current R301 category. If your client chooses to continue with review of the action under the R315 category, the PRIA clock will reset at 21-days from receipt of the outstanding balance between the R301 and R315 categories.

You indicated during our phone call that you expected to be able to provide the revised forms addressing the deficiency this afternoon or tomorrow. Please cc: me on your email to Venus and indicate whether your client agrees to the recode to R315. I will proceed with getting the action recoded once I have received your indication that this is the preferred path forward.

Best regards, Steve

Stephen A. Schaible, PRIA Ombudsman
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
ph: (703)308-9362

SPRING TRADING COMPANY

49621400

Venus Eagle
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

April 17, 2015

Dear Ms. Eagle:

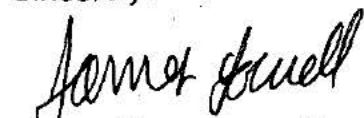
Re: Application for registration for Neove Spot On #001, EPA Company number 091090, from Shanghai Neway Animal Health Co., Ltd, Rm509, 1438 Shan Xi Bei Road, Shanghai, China, 200060. A receipt for the PRIA-3 category R-301 payment is attached.

The following documents are enclosed to support the tolerance exemption request for this petition:

Title of Study	MRID Number
Cover letter and Transmittal Document, Label copies EPA Form 8570-1, Application form, and completed forms, 8570-4, 8570-27, 8570-34, 8570-35, 8570-36 and 8570-37.	
Product Chemistry Volume – OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750 and 830.1800.	49621401
Product Chemistry Volume – OPPTS – 830.6302, 830.6303, 830.6304, 830.7100, and 830.7300.	49621402
Product Chemistry Volume – OPPTS – 830.6317 and 830.6320.	49621403

If you have any questions please call me on 832-722-5113.

Sincerely:



James Yowell, President
Spring Trading Company
Agent for Shanghai Neway Animal Health Co., Ltd.

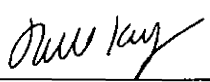
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

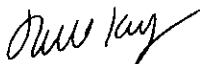
Date June 10, 2015			EPA Reg. No./File Symbol 91090-G		Page 1 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China			Product Neove Spot On #001		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1600	Description of Materials Used to Produce the Product	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1620	Description of Production Process				Not required ¹
830.1650	Description of Formulation Process	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1670	Discussion of Formation of Impurities	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1700	Preliminary Analysis				Not Required ²
830.1750	Certified Limits	49621401	Shanghai Neway Animal Health Co.	OWN	
830.1800	Enforcement Analytical Method	49621401	Shanghai Neway Animal Health Co.	OWN	
830.6302	Color	49621402	Shanghai Neway Animal Health Co.	OWN	
830.6303	Physical State	49621402	Shanghai Neway Animal Health Co.	OWN	
Signature 			Name and Title Janelle Kay, Agent		Date June 10, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date June 10, 2015		EPA Reg. No./File Symbol 91090-G		Page 2 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China		Product Neove Spot On #001			
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304	Odor	49621402	Shanghai Neway Animal Health Co.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required ³
830.6314	Oxidation/Reduction: Chemical Incompatibility				Waiver
830.6315	Flammability				Waiver
830.6316	Explodability				Waiver
830.6317	Storage Stability	49621403	Shanghai Neway Animal Health Co.	OWN	
830.6319	Miscibility				Not required ⁴
830.6320	Corrosion Characteristics	49621403	Shanghai Neway Animal Health Co.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required ⁵
830.7000	pH	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7050	UV/Visible Absorption				Not required ⁶
830.7100	Viscosity	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7200	Melting Point/Melting Range				Not required ⁶
Signature 			Name and Title Janelle Kay, Agent		Date June 10, 2015

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date June 10, 2015		EPA Reg. No./File Symbol 91090-G		Page 3 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China		Product Neove Spot On #001			
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Point/Boiling Range				Not required ⁶
830.7300	Density/Relative Density/Bulk Density	49621402	Shanghai Neway Animal Health Co.	OWN	
830.7370	Dissociation Constants in Water				Not required ⁶
830.7520	Particle size, fiber length, diameter distribution				Not required
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required ⁶
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required ⁶
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not required ⁶
870.1100	Acute Oral Toxicity: Rat	43679601		OLD	
870.1200	Acute Dermal Toxicity: Rat	43679602		OLD	
870.1300	Acute Inhalation Toxicity: Rat	43679603		OLD	Waiver
Signature 			Name and Title Janelle Kay, Agent		Date June 10, 2015

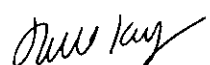
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DATA MATRIX

Date June 10, 2015			EPA Reg. No./File Symbol 91090-G		Page 4 of 4
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. Rm 509, 1438 Shang Xi Bei Rd. Shanghai 200060, China			Product Neove Spot On #001		
Ingredient Imidacloprid (CAS No. 105827-78-9, Chemical Code 129099)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation: Rabbit	43679604		OLD	
870.2500	Primary Dermal Irritation	43679605		OLD	
870.2600	Dermal Sensitization	43679606		OLD	
870.7200	Companion Animal Safety	43679607 43679608 44099801 44179801		OLD OLD OLD OLD	
810.3300	Product Performance	43679609 43679610 44256901 44256902 44256903			
Generic Data Requirements					
Neuve Spot On #001 qualifies for the Formulator's Exemption for imidacloprid generic data requirements.					
Signature 			Name and Title Janelle Kay, Agent		Date June 10, 2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Shanghai Neway Animal Health Co., 4110 136th St. Ct. NW; Gig Harbor, WA 98332; 253-853-7369	EPA Registration Number/File Symbol 91090-G
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date June 10, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor; domestic animals	Product Name Neove Spot On #001

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date June 10, 2015	Typed or Printed Name and Title Janelle Kay; Agent
---------------	-----------------------	---

Schaible, Stephen

From: Janelle Kay <Janelle@PyxisRC.com>
Sent: Wednesday, June 10, 2015 6:05 PM
To: Schaible, Stephen
Cc: Eagle, Venus
Subject: EPA File Symbol 91090-G
Attachments: Neway LOA_product specific.pdf; 20150610 Certification with Respect to Citation_signed.pdf; 20150610 Agency matrix.pdf; 20150610 Public matrix.pdf

Steve/Venus,

I hope all is well with both of you. I understand you've been in communication with Jim Yowell regarding a pending application for Shanghai Neway (EPA File Symbol 91090-G) for a product called Neove Spot On #001. Shanghai Neway has decided to change agents to Pyxis for this product (not for the company) and I've provided a copy of the LOA attached.

First, I understand there were some deficiencies with the data matrix (i.e. failure to cite target animal safety data) and it appears there were also inconsistencies between the citations and the Certification with Respect to Citation of Data. I have corrected these errors in the attached matrices (Agency and Public) and certification.

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I look forward to hearing from you. In the meantime, please let me know if you have any questions or need any additional information.

Regards,

Janelle

Janelle Kay
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332
(T): 1-253-853-7369
(F): 1-253-853-5516
(E): Janelle@PyxisRC.com

Given to Steve on 5/26 to recode
to R315

Completion of 21-Day Content Screen

PM- 1

EPA Reg. # (File Symbol) 91 090-G

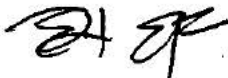
Decision # D

Data package delivered to
you on _____.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team



Memorandum

Date: 5/8/15

To: PM 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 26, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-503658
EPA File Symbol or Registration Number: 91090-G
Product Name: NEOVE SPOT ON #001
EPA Receipt Date: 22-Apr-2015
EPA Company Number: 91090
Company Name: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

JANELLE KAY
PYXIS REGULATORY CONSULTING, INC.
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
4110 136TH STREET, NW
GIG HARBOR, WA 98332

SUBJECT: ,Recoding of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has recoded your application that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

This action has been recoded as action code R315:

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

The fee for action code R315 with the 75% fee waiver is \$2,100. Payment has been received in the amount of \$452. Please remit payment in the amount of \$1,648 with 14 days to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:

U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (314) 425-1818

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

A PRIA decision time review period will not start until the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

April 30, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SPRING TRADING COMPANY
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
10805 W. TIMBERWAGON CIRCLE
SPRING, TX 77380-4030

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-APR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 967411

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☒ No

Billable: ☒ Yes ☒ No

Company: 91090 SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.



Risk Manager: Registration Division, Risk Management Team 1

Product #: 91090-G

Product Name: NEOVE SPOT ON #001

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 17-Apr-2015

OPP Rec'd Date: 22-Apr-2015

Front End Date: 22-Apr-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for registration for Neove Spot On #100.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

SPRING TRADING COMPANY

49621400

Venus Eagle
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

April 17, 2015

Dear Ms. Eagle:

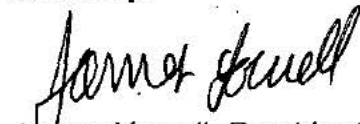
Re: Application for registration for Neove Spot On #001, EPA Company number 091090, from Shanghai Neway Animal Health Co., Ltd, Rm509, 1438 Shan Xi Bei Road, Shanghai, China, 200060. A receipt for the PRIA-3 category R-301 payment is attached.

The following documents are enclosed to support the tolerance exemption request for this petition:

Title of Study	MRID Number
Cover letter and Transmittal Document, Label copies EPA Form 8570-1, Application form, and completed forms, 8570-4, 8570-27, 8570-34, 8570-35, 8570-36 and 8570-37.	
Product Chemistry Volume – OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750 and 830.1800.	49621401
Product Chemistry Volume – OPPTS – 830.6302, 830.6303, 830.6304, 830.7100, and 830.7300.	49621402
Product Chemistry Volume – OPPTS – 830.6317 and 830.6320.	49621403

If you have any questions please call me on 832-722-5113.

Sincerely:



James Yowell, President
Spring Trading Company
Agent for Shanghai Neway Animal Health Co., Ltd.

10805 West Timberwagon Circle
Spring, TX 77380-4030

Office Phone: 877-227-2597
Consultant Phone: 832-722-5113
Email: Spring_Trading@yahoo.com

21-Day Screen Completed by
Contractor

21-Day Expires on 5-13-15

Jacket # 91090-G

MRID# 496214

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

SHAUNTA HILL

NEW APPLICATIONS

DATE: APR 22 2015

FILE REG NUMBER: 91090-G

FEP (OPPIN ENTRY) C.D. APR 22 2015

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD RD / BPPD

JACKET TO SHELF (DATA)

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4-22-15

Experts In-Processing Signature: B.D.

Date 4-24-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>91090-C</u>		EPA Receipt Date: <u>4-22-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>Non-food</u>			X		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

- Required forms are complete.

Inerts: Pass

- Approved for non-food use.

11-3: Pass

MRIID - 496314

Status: Pass

TJ 5/11/15

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 23, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-503658
EPA File Symbol or Registration Number: 91090-G
Product Name: NEOVE SPOT ON #001
EPA Receipt Date: 22-Apr-2015
EPA Company Number: 91090
Company Name: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

MR. JAMES R. YOWELL
SPRING TRADING COMPANY
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
10805 W. TIMBERWAGON CIRCLE
SPRING, TX 77380-4030

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R301

NEW PRODUCT; IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT; REGISTERED SOURCE OF ACTIVE INGREDIENT; SELECTIVE DATA CITATION ONLY FOR DATA ON PRODUCT CHEMISTRY / ACUTE TOXICITY / PUBLIC HEALTH PEST EFFICACY, WHERE APPLICANT DOES NOT OWN ALL REQUIRED DATA NOR HAS AUTHORIZATION LETTER FROM DATA OWNER;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

A handwritten signature in black ink, appearing to be "J. H. Smith".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{967411C~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 4/23/15

Remarks:

similarity clinic

Receipt for Section 3

S: 967411

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☒ No

Billable: ☒ Yes ☒ No

Company: 91090 SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.



Risk Manager: Registration Division, Risk Management Team 1

Product #: 91090-G Product Name: NEOVE SPOT ON #001

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 17-Apr-2015

OPP Rec'd Date: 22-Apr-2015

Front End Date: 22-Apr-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for registration for Neove Spot On #100.

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

CSF

View/Edit

James Yowell

From: notification@pay.gov
Sent: Thursday, April 16, 2015 1:45 PM
To: James Yowell
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

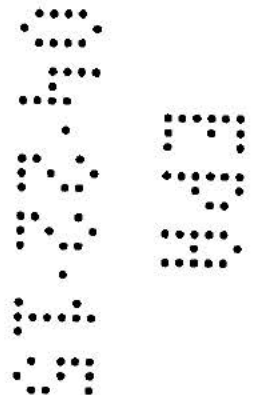
Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25KRM6H4
Agency Tracking ID: 74788317759
Transaction Type: Sale
Transaction Date: 04/16/2015 02:44:45 PM EDT

Account Holder Name: James Yowell

Transaction Amount: \$451.50
Billing Address: 203 Dogwood Trail
Billing Address 2:
City: Magnolia
State/Province: Texas
Zip/Postal Code: 773545201
Country:
Card Type: MasterCard
Card Number: *****6626

Registration Number:
Company Name: Shanghai Neway Animal Hea
Company Number: 91090
Action Code: R-301

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



2020



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 091090	2. EPA Product Manager <u>Venus Eagle</u>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Neove Spot On #001	PM#	
5. Name and Address of Applicant (Include ZIP Code) Shanghai Newway Animal Health Co., Ltd Rm509, 1438 Shan Xi Bei Road, Shanghai, China 200000 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>11556-117(119,120,122)</u> Product Name <u>Advantage 10(20,55,100) Topical Solution</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt. 1.3g/tube	No. per container 1		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.4ml to 4.0ml		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James Yowell	Title Consultant	Telephone No. (Include Area Code) 877-227-2597
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>James Yowell</u>	3. Title <u>Consultant</u>	
4. Typed Name <u>James Yowell</u>	5. Date <u>17 April 2015</u>	

22
22
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22

Handwritten signature

SPRING TRADING COMPANY

Venus Eagle
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Room S-4900, 4th Floor
Arlington, VA 22202

April 17, 2015

Dear Ms. Eagle:

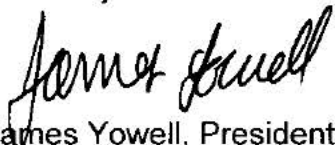
Re: Application for registration for Neove Spot On #001, EPA Company number 091090, from Shanghai Neway Animal Health Co., Ltd, Rm509, 1438 Shan Xi Bei Road, Shanghai, China, 200060. A receipt for the PRIA-3 category R-301 payment is attached.

The following documents are enclosed to support the tolerance exemption request for this petition:

Title of Study	MRID Number
Cover letter and Transmittal Document, Label copies EPA Form 8570-1, Application form, and completed forms, 8570-4, 8570-27, 8570-34, 8570-35, 8570-36 and 8570-37.	
Product Chemistry Volume – OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750 and 830.1800.	
Product Chemistry Volume – OPPTS – 830.6302, 830.6303, 830.6304, 830.7100, and 830.7300.	
Product Chemistry Volume – OPPTS – 830.6317 and 830.6320.	

If you have any questions please call me on 832-722-5113.

Sincerely:



James Yowell, President
Spring Trading Company
Agent for Shanghai Neway Animal Health Co., Ltd.

16805 West Timberwagon Circle
Spring, TX 77380-4030

Office Phone: 877-227-2597
Consultant Phone: 832-722-5113
Email: Spring_Trading@yahoo.com

TRANSMITTAL DOCUMENT

Submitter:

Shanghai Neway Animal Health Co.,Ltd, Rm509,
1438 Shan Xi Bei Road, Shanghai,
China, 200060EPA

Company Number: 91090

Company Contact: James Yowell
Typed Name of Signer: James Yowell, Agent

Phone: 832-622-3960

Email Address: james@springtradingcompany.com

Regulatory Action in Support of Which this Package Id Submitted:

Application for registration for Neove Spot On #001

Submission Date:

April 17, 2015

List of Submitted Documents:

Title of Study	MRID Number
Cover letter and Transmittal Document, Label copies EPA Form 8570-1, Application form, and completed forms, 8570-4, 8570-27, 8570-34, 8570-35, 8570-36 and 8570-37.	
Product Chemistry Volume – OPPTS 830.1550, 830.1600, 830.1650, 830.1670, 830.1750 and 830.1800.	
Product Chemistry Volume – OPPTS – 830.6302, 830.6303, 830.6304, 830.7100, and 830.7300.	
Product Chemistry Volume – OPPTS – 830.6317 and 830.6320.	

9 3
2 4
3 4
4
4 4
4



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Shanghai Neway Animal Health Co., Ltd Rm509, 1438 Shan Xi Bei Road, Shanghai China 200060	EPA File Symbol/Registration Number
	Product Name Neove Spot On #001
	Date of Confidential Statement of Formula (EPA Form 8570-4) 4/15/15

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

Imidacloprid

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid	[REDACTED]	[REDACTED]
<p>*Product ingredient source information may be entitled to confidential treatment*</p>		
Signature <i>James Howell</i>	Name and Title JAMES Howell, CONSULTANT	Date 15 April 2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data.

Applicant's/Registrant's Name, Address, and Telephone Number Shanghai Neway Animal Health Co., Ltd. Rm509, 1438 Shan Xi Bei Road, Shanghai, China. +86 21	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s) Imidacloprid	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): For the prevention and treatment of flea and lice infestations on dogs.	Product Name: Neove Spot On #001

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>James Yowell</i>	Date 4/15/15	Typed or Printed Name and Title JAMES Yowell, consultant
----------------------------------	-----------------	---

R 300 and 301

100% identical (repack): YES or NO (circle one)

{if **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	✓	
830.1650	Description of formulation process	✓	
830.1670	Discussion on the formation of impurities	✓	
830.1700	Preliminary analysis	✓	
830.1750	Certified limits (158.345)	✓	
830.1800	Enforcement analytical method	✓	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color		
830.6303	Physical State		
830.6304	Odor		
830.6314	Oxidation/Reduction (Chemical incompatibility)		
830.6315	Flammability		
830.6316	Explosibility		
830.6317	Storage stability		
830.6319	Miscibility		
830.6320	Corrosion Characteristics		
830.6321	Dielectric Breakdown voltage		
830.7000	pH		
830.7100	Viscosity		
830.7300	Density		

Self-citation form

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

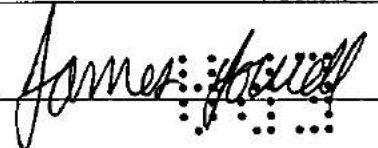
Not Required

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			

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DATA MATRIX

Date 04/17/2015			EPA Reg. No./File Symbol 91090		Page 1 of 9
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354			Product Neove Spot On #001		
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition		Shanghai Neway Animal Health Co.	OWN	
830.1600	Description of Materials Used to Produce the Product		Shanghai Neway Animal Health Co.	OWN	
830.1650	Description of Formulation Process		Shanghai Neway Animal Health Co.	OWN	
830.1670	Discussion of Formation of Impurities		Shanghai Neway Animal Health Co.	OWN	
830.1700	Preliminary analysis		Shanghai Neway Animal Health Co.		
830.1750	Certified Limits		Shanghai Neway Animal Health Co.	OWN	
830.1800	Enforcement Analytical Method		Shanghai Neway Animal Health Co.	OWN	
830.1900	Submittal of Samples		Shanghai Neway Animal Health Co.		1
830.6302	Color		Shanghai Neway Animal Health Co.	OWN	
830.6303	Physical State		Shanghai Neway Animal Health Co.	OWN	
830.6304	Odor		Shanghai Neway Animal Health Co.	OWN	
830.6314	Oxidation / reduction		Shanghai Neway Animal Health Co.		5
830.6315	Flammability/Flame Extension		Shanghai Neway Animal Health Co.		2
830.6316	Explodability		Shanghai Neway Animal Health Co.		3
830.6317	Storage Stability		Shanghai Neway Animal Health Co.	OWN	
830.6319	Miscibility		Shanghai Neway Animal Health Co.		4
830.6320	Corrosion Characteristics		Shanghai Neway Animal Health Co.	OWN	
830.6321	Dielectric Breakdown Voltage		Shanghai Neway Animal Health Co.		6
830-7000	pH		Shanghai Neway Animal Health Co.	OWN	
860-7100	Viscosity		Shanghai Neway Animal Health Co.	OWN	
830.7300	Density		Shanghai Neway Animal Health Co.	OWN	
Signature 			Name and Title James Yowell, Consultant		Date 04/17/2015

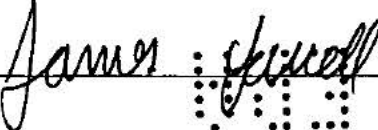
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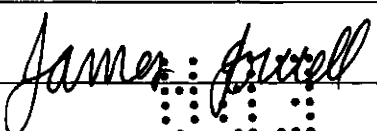
DATA MATRIX

Date 04/17/2015			EPA Reg. No./File Symbol 91090		Page 2 of 9
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354			Product Neove Spot On #001		
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3100, 810.3200, 810.3300, 810.3500	Efficacy			FOR	
ECOLOGICAL EFFECTS					
850.2100	Avian Acute Oral Toxicity			FOR	
	Avian Acute Oral - Duck			FOR	
850.2200	Avian Dietary Toxicity - Quail			FOR	
850.2200	Avian Dietary Toxicity - Duck			FOR	
850.2300	Avian Reproduction - Quail			FOR	
850.2300	Avian Reproduction - Duck			FOR	
	Acute Wild Mammal Toxicity- Rat			FOR	
850.1075	Fish Toxicity Bluegill			FOR	
850.1075	Freshwater Fish Toxicity Rainbow Trout			FOR	
850.1075	Freshwater Fish Toxicity Rainbow Trout - TEP			FOR	
850.1010	Freshwater Invertebrate Toxicity			FOR	
850.5400	Aquatic Plant Growth			FOR	
TOXICOLOGY					
870.1100	Acute Oral Toxicity - Rat	45096904	Bayer Health Care LLC	OLD	
870.1200	Acute Dermal Toxicity - Rabbit/Rat	45096905	Bayer Health Care LLC	OLD	
870.2400	Primary Eye Irritation - Rabbit	45096907	Bayer Health Care LLC	OLD	
Signature 			Name and Title James Yowell, Consultant		Date 4/17/2015

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DATA MATRIX


Date 4/17/2015			EPA Reg. No./File Symbol 91090		Page 3 of 9
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354			Product Neove Spot On #001		
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1300	Acute Inhalation	45096906	Bayer Health Care LLC	OLD	
870.2500	Primary Skin Irritation	45096908	Bayer Health Care LLC	OLD	
870.2600	Dermal Sensitization	45096909	Bayer Health Care LLC	OLD	
870.3100	Subchronic Oral Toxicity: 90- Day Study Rodent	cite all		FOR	
870.3150	Subchronic Oral Toxicity: 90- Day Study Non-rodent	cite all		FOR	
850.1010	21-Day Dermal - Rabbit/Rat	cite all		FOR	
850.5400	Developmental Toxicity - Rat	cite all		FOR	
870.3200	Developmental Toxicity - Rabbit	cite all		FOR	
870.3700	2-Generation Reproduction - Rat	cite all		FOR	
870.3700	Chronic Feeding Toxicity - Rat	cite all		FOR	
870.3800	2-Generation Reproduction - Rat	cite all		FOR	
870.4100	Chronic Feeding Toxicity - Rat	cite all		FOR	
870.4100	Chronic Feeding Toxicity - Nonrodent	cite all		FOR	
870.4200a	Oncogenicity Rat	cite all		FOR	
870.4200	Carcinogenicity Mice	cite all		FOR	
870.4300	Combined Chronic Toxicity/Carcinogenicity: Rats	cite all		FOR	
870.5100	Bacterial Reverse Gene Mutation	cite all		FOR	
870.7485	General Metabolism	cite all		FOR	
Signature 			Name and Title James Yowell, Consultant		Date 4/17/2015

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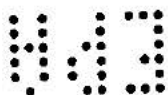
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DATA MATRIX

Date 4/17/2015			EPA Reg. No./File Symbol 91090		page 4 of 9
Applicant's/Registrant's Name & Address Shanghai Newway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354			Product Neove Spot On #001		
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ENVIRONMENTAL FATE		cite all		FOR	
835.2120	Hydrolysis	cite all		FOR	
835.2240	Photodegradation - Water	cite all		FOR	
835.4400	Anaerobic Aquatic Metabolism	cite all		FOR	
835.4300	Aerobic Aquatic Metabolism	cite all		FOR	
835.1240	Leaching/Adsorption/Desorption	cite all		FOR	
835.1410	Laboratory Volatilization	cite all		FOR	
165-4	Bioaccumulation in Fish	cite all		FOR	
OCCUPATIONAL/RESIDENTIAL EXPOSURE	ALL REQUIREMENTS			FOR	
Signature 			Name and Title James Yowell, Consultant		Date 4/17/2015

Based on EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.


Agency Internal Use Copy

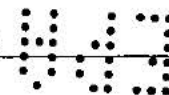


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DATA MATRIX

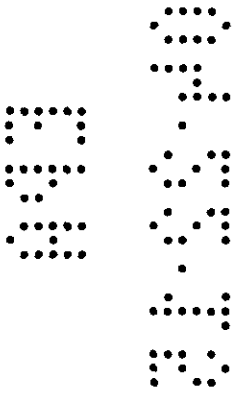
Date 4/17/2015		EPA Reg. No./File Symbol 91090		Page 5 of 9	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354		Product Neove Spot On #001			
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Shanghai Neway Animal Health Co.	Status	
			Shanghai Neway Animal Health Co.	OWN	
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			Shanghai Neway Animal Health Co.	OWN	
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			Shanghai Neway Animal Health Co.	OWN	
			Shanghai Neway Animal Health Co.	OWN	
			Shanghai Neway Animal Health Co.	OWN	
Signature			Name and Title		Date
			James Yowell, Consultant		4/17/2015



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DATA MATRIX

Date 4/17/2015		EPA Reg. No./File Symbol 91090		Page 6 of 9	
Applicant's/Registrant's Name & Address Shanghai Newway Animal Health Co. C/O Spring Trading Company, 203 Dogwood Trail, Magnolia, Texas 77354		Product Neove Spot On #001			
Ingredient(s) Imidacloprid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				FOR	
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			Bayer Health Care LLC.	OLD	
			Bayer Health Care LLC.	OLD	
			Bayer Health Care LLC.	OLD	
Signature 			Name and Title James Yowell, Consultant		Date 4/17/2015



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DATA MATRIX

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DATA MATRIX

Page 8 of 9

Neove Spot On #001

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Signature Jama Bruell
Based on EPA Form 8570-35 (9-97) E

4/17/2015

DATA MATRIX FOOTNOTES

- | | |
|---|--|
| 1. Submittal of Samples | Samples will be provided if requested. |
| 2. Flammability/Flame
the inert
Extension | Not Applicable. Neither the technical grade active ingredient nor ingredients are considered as flammable. |
| 3. Explosability
the inert | Not Applicable. Neither the technical grade active ingredient nor Ingredients are considered as an explosion hazard. |
| 4. Miscibility
petroleum Solvents. | Not Applicable. This product is not intended to be diluted with |
| 5. Oxidation/reduction
reducing agent. | Not applicable, the product does not contain an oxidizing or |
| 6. Dielectric Breakdown
equipment. | Not applicable the product will not be used around electrical |

OWN: I am the Original Data Submitter for this study.

EXC: I have obtained written permission of the Original Data Submitter to cite this exclusive-use study in support of this application.

PER: I have obtained the permission of the Original Data Submitter to use this study in support of this application.

OLD: The study was submitted more than 15 years ago and all periods of compensation have expired.

PL: The study is in the public literature.

PAY: I have notified in writing the Original Data Submitter or, if the cite-all method is used, all companies listed in the most current Data Submitters List for this ingredient, and have offered (a) to pay compensation in accordance with FIFRA sections 3(c)(1)(F) and/or 3(c)(2)(B), and (b) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study(ies).

GAP: This Guideline data requirement is a data gap as defined in 40 CFR sections 152.83(a) and 152.96.

FOR: I am taking the formulator's exemption for this ingredient only. Other columns of this line should be marked "NA". However, if this product is to be registered/reregistered for additional uses for which the purchased EPA registered ingredient is not supported, additional data must be submitted or cited here to support those uses.

Note: If additional explanation is needed, enter a footnote number in this column and attach the corresponding explanation.

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SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: Neove Spot On #001		2. Reg. No.
3. COMPANY NAME: Shanghai Neway Animal Health Co., Ltd		4. SUBMISSION DATE:
5. FIRST SUBMISSION <input checked="" type="checkbox"/> 6. RESUBMISSION <input type="checkbox"/>	7. PESTICIDE TYPE: Insecticide	10. REGISTRATION <input checked="" type="checkbox"/>
8. FORMULATED MANUFACTURING-USE PRODUCT <input type="checkbox"/> or 9. END-USE PRODUCT <input checked="" type="checkbox"/>		11. REREGISTRATION <input type="checkbox"/>
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN):		12. REREG CASE #
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)

-6302	Color	Yellow, brownish	NW-P03-E02-1
-6303	Physical State	Liquid	NW-P03-E02-2
-6304	Odor	Weak characteristic	NW-P03-E02-3
-6314	Oxidation/Reduction: Chemical Incompatibility		
-6315	Flammability/Flame Extension		
-6316	Explosibility		
-6317	Storage Stability	Very little change in the concentrations of active ingredient when stored for 14 days under elevated temperatures in commercial packaging material.	NW-P03-E03
-6319	Miscibility		
-6320	Corrosion Characteristics	No evidence of corrosion of the container was observed when the test substance was stored for 14 days under elevated temperatures in commercial packaging material.	NW-P03-E03
-6321	Dielectric Breakdown Voltage		
-7000	pH		
-7100	Viscosity		NW-P03-E02-4
-7300	Density/Relative Density/ Bulk Density		NW-P03-E02-5

Figure 1 displays a 4x4 grid of 16 small square plots, each containing a different spatial pattern of black dots. The patterns vary in density, distribution, and arrangement, representing different realizations of a spatial process. The plots are arranged in four rows and four columns.



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**SELF-CERTIFICATION STATEMENT FOR THE
 PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)**

Product Name: Neove Spot On #001

Reg. No./File Symbol No.
 (if known) or Company No. 091090

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): Shanghai Neway Animal Health Co., Ltd and that the values of the properties reported are reliable.

I further certify that such data were generated in substantial conformity with OPPTS Test Guideline Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name:

JAMES Yowell

Title:

CONSULTANT

Telephone No.

832-722-5113

Applicant's Signature:

James Yowell

Date:

15 April 2015

EPA Form 8570-37 (12-2003)

Attach-2

MASTER LABEL

[Front Panel]

Neove Spot On #001

Alternate Brand Names

ImidaCare for Dogs [& or Puppies]

ImidaStar for Dogs [& or Puppies]

PetImida for Dogs [& or Puppies]

Once a Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- One treatment prevents further flea infestation for at least four weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [biting, chewing] lice
- For treatment and prevention of [biting, chewing] lice [infestations]
- Controls existing [biting, chewing] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [biting, chewing] lice [infestations]
- Provides effective control of [biting, chewing] lice [infestations]
- Kills [biting, chewing] lice and prevents further infestations
- For treatment and prevention of infestations with [biting, chewing] lice
- Waterproof
- Fragrance free

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0

EPA Est. No. 091090-XXX-X

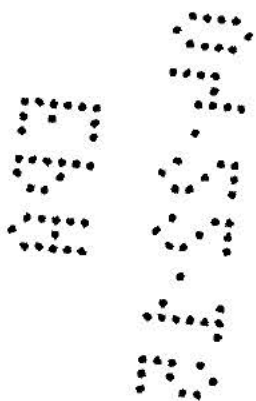
EPA Reg. No. 091090 -XXX

KEEP OUT OF REACH OF CHILDREN
CAUTION

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.



Icon size 1.5cm x 1.5cm



[Back Panel]

Once a Month Topical Flea and Lice Treatment	
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 3 1/2 to 10 lbs	
OR	
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs	
OR	
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs	
OR	
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
To Physician: Treat the patient symptomatically.	

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the

Note: [Brackets indicate alternate language]

labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

Side Effects Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



Icon size 1.5cm x 1.5cm

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing $3\frac{1}{2}$ - 10 lbs.

OR

11 - 20 lbs

OR

21 - 55 lbs

OR

Over 55 lbs

- Do not use on other animals.
- Do not apply to puppies or dogs weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: [X] Tube(s) each 0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

Manufactured For

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

(Company XXX)

(Company YYY)

Made in China

Note: [Brackets indicate alternate language]

(Made in USA)

(Made in France)

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99

[Back Panel and/or Insert]

Once a Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.



HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as shown. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.

Visuals depicting how to open blister pack

3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN BLISTER PACK"
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.

Visuals depicting Application to Animal

4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every

Note: [Brackets indicate alternate language]

seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

Larval flea stages in the dog's surroundings are killed following contact with [Product Name] treated dogs.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container.

If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

(Company XXX)

(Company YYY)

warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

(Company XXX)

(Company YYY)

MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

(Company XXX)

(Company YYY)

is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Note: [Brackets indicate alternate language]

[Label on Individual Tube]

(Product Name)

9.1% Imidacloprid

0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 091090-XXX

CAUTION

Keep Out of Reach of Children

Read the Entire Label before Use

NEWAY

(Company XXX)

(Company YYY)

Lot No. 0000000

0000000

Note: [Brackets indicate alternate language]

[Label on blister card; one card containing X tubes]

(Product Name)

For External Use Only on **Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs**

OR

Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

9.1% Imidacloprid

[X] - 0.014 fl. oz. (0.4 mL)

OR

[X] - 0.034 fl. oz. (1.0 mL)

OR

[X] - 0.084 fl. oz. (2.5 mL)

OR

[X] - 0.135 fl. oz. (4.0 mL)

EPA Reg. No. 091090-XXX

NEWAY

(Company XXX)

(Company YYY)



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2

MASTER LABEL

[Front Panel]

Neove Spot On #001

Alternate Brand Names

ImidaCare for Dogs [& or Puppies]

ImidaStar for Dogs [& or Puppies]

PetImida for Dogs [& or Puppies]

Once a Month Topical Flea and Lice Treatment
For Use Only on **Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs**

OR

Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

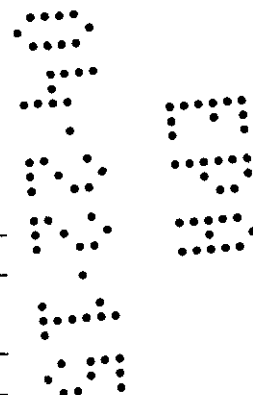
For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- One treatment prevents further flea infestation for at least four weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient, easy to apply
- Kills [biting, chewing] lice
- For treatment and prevention of [biting, chewing] lice [infestations]
- Controls existing [biting, chewing] lice infestations
- Dual protection (against fleas and lice)
- Treats, prevents and controls [biting, chewing] lice [infestations]
- Provides effective control of [biting, chewing] lice [infestations]
- Kills [biting, chewing] lice and prevents further infestations
- For treatment and prevention of infestations with [biting, chewing] lice
- Waterproof
- Fragrance free

Active Ingredient	Content (% By Weight)
Imidacloprid [CAS 138261-41-3]	9.1
Other Ingredients	90.9
Total	100.0

EPA Est. No. 091090-XXX-X

EPA Reg. No. 091090 -XXX

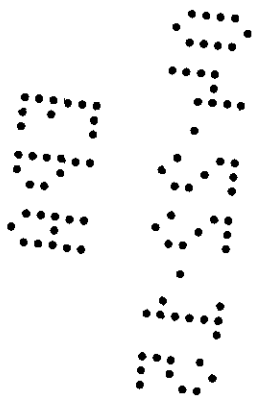


KEEP OUT OF REACH OF CHILDREN
CAUTION

- See Back Panel for First Aid and Precautionary Statements.
- For Directions for Use & Storage and Disposal (instructions), see supplemental labeling inside.



Icon size 1.5cm x 1.5cm



[Back Panel]

Once a Month Topical Flea and Lice Treatment	
For Use Only on <u>Dogs and Puppies 7 Weeks and Older and Weighing 3 1/2 to 10 lbs</u>	
OR	
<u>Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs</u>	
OR	
<u>Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs</u>	
OR	
<u>Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs</u>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by the poison control center or doctor • Do not give anything by mouth to an unconscious person
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.
NOTES	
To Customer: Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
To Physician: Treat the patient symptomatically.	

HAZARDS TO DOMESTIC ANIMALS

For External Use Only Do not use on puppies under seven weeks of age or weighing less than the

Note: [Brackets indicate alternate language]

labeled bodyweight. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

Side Effects Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian.

DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



Icon size 1.5cm x 1.5cm

RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing $3\frac{1}{2}$ - 10 lbs.

OR

11 - 20 lbs

OR

21 - 55 lbs

OR

Over 55 lbs

- Do not use on other animals.
- Do not apply to puppies or dogs weighing less than the labeled bodyweight.
- Do not apply more than one tube per treatment.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: [X] Tube(s) each 0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

Manufactured For

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD
Rm509, 1438 Shang Xi Bei Rd, Shanghai 200060, China

(Company XXX)

(Company YYY)

Made in China

Note: [Brackets indicate alternate language]

(Made in USA)
(Made in France)

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1. The first step in the process of the development of the new curriculum is the identification of the needs of the community. This is done by the community members themselves, who are consulted about their needs and expectations. The results of this consultation are then used to develop the curriculum.

1. *What is the main purpose of the study?*
 2. *What are the research objectives?*
 3. *What is the research methodology?*
 4. *What are the findings of the study?*
 5. *What are the conclusions of the study?*
 6. *What are the limitations of the study?*
 7. *What are the implications of the study?*
 8. *What are the future research directions?*
 9. *What are the contributions of the study?*
 10. *What are the key words of the study?*

[Back Panel and/or Insert]

Once a Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs
OR
Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.



HOW TO OPEN BLISTER PACK

1. Snap off one section of the blister card along the tube segment line.
2. Use scissors to cut across the top of the section as shown. Or use scissors to open by cutting carefully into the blister cavity across the small side, close to the cap of the tube.

Visuals depicting how to open blister pack

3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

HOW TO APPLY

1. Remove one applicator tube from the package. See "HOW TO OPEN BLISTER PACK"
2. Hold applicator tube in an upright position facing away from you and your dog's face and eyes. Screw the cap off tube.
3. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. *Do not get this product in your dog's eyes or allow your dog to ingest this product.* Do not allow the product to run off.

Visuals depicting Application to Animal

4. Discard empty tube as described in the Storage and Disposal section.
5. Under normal conditions the product is effective for a month. For severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every

Note: [Brackets indicate alternate language]

seven days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Product Name] kills fleas and may reduce the incidence of this condition.

[Product Name] kills fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon the climatic conditions.

Larval flea stages in the dog's surroundings are killed following contact with [Product Name] treated dogs.

[Product Name] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets.

Pesticide Disposal and Container Handling: Non-refillable container.

If empty: Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

(Company XXX)

(Company YYY)

warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

(Company XXX)

(Company YYY)

MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

(Company XXX)

(Company YYY)

is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Note: [Brackets indicate alternate language]

[Label on Individual Tube]

(Product Name)

9.1% Imidacloprid

0.014 fl. oz. (0.4 mL)

OR

0.034 fl. oz. (1.0 mL)

OR

0.084 fl. oz. (2.5 mL)

OR

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 091090-XXX

CAUTION

Keep Out of Reach of Children

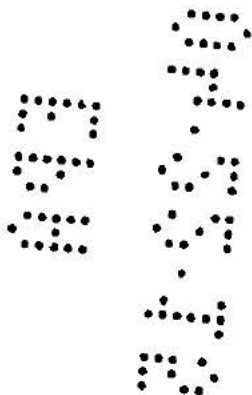
Read the Entire Label before Use.

NEWAY

(Company XXX)

(Company YYY)

Lot No. 0000000



Note: [Brackets indicate alternate language]

[Label on blister card; one card containing X tubes]

(Product Name)

For External Use Only on Dogs and Puppies 7 Weeks and Older and Weighing 3½ to 10 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing 11 to 20 lbs

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Dogs and Puppies 7 Weeks and Older and Weighing 21 to 55 lbs

OR

Dogs and Puppies 7 Weeks and Older and Weighing over 55 lbs

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NEWAY

(Company XXX)

(Company YYY)

